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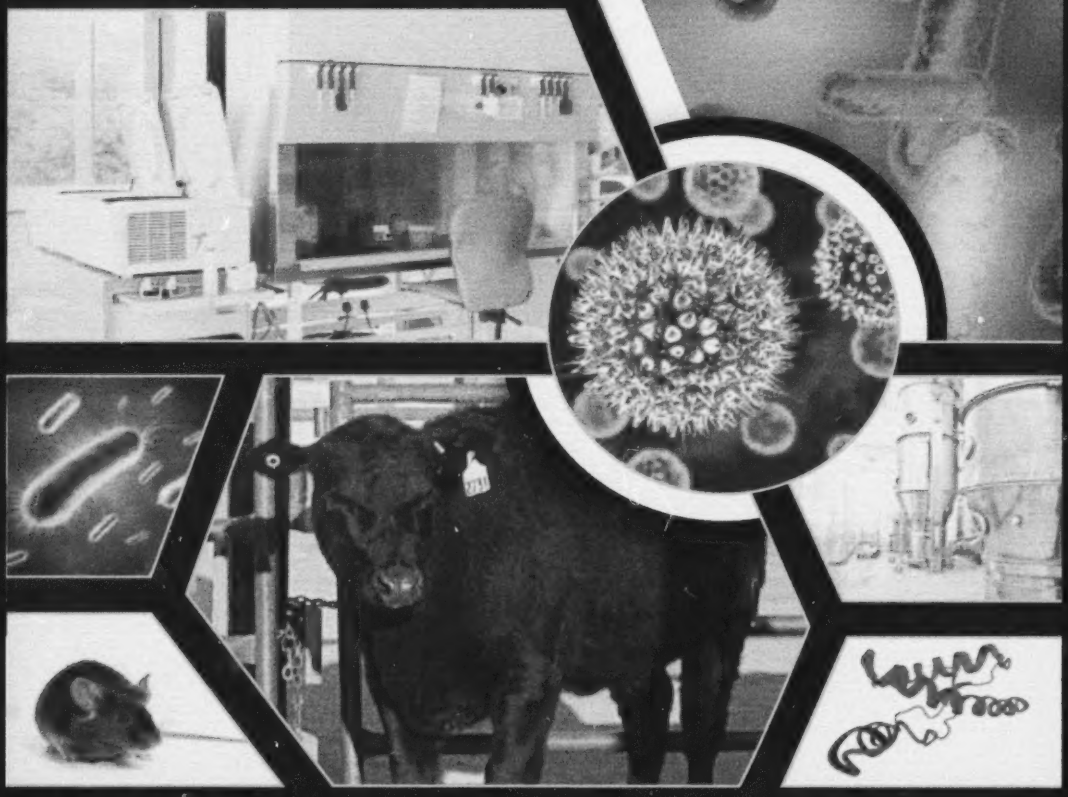
CANADIAN BIOSAFETY STANDARD

for Facilities Handling or Storing Human and Terrestrial Animal Pathogens and Toxins



Second Edition

Canada

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PREFACE

PREFACE

The Government of Canada's *Canadian Biosafety Standard* (CBS), 2nd Edition, 2015, is a harmonized national standard for the handling or storing of human and terrestrial animal pathogens and toxins in Canada. Activities in Canada involving human and animal pathogens and toxins are regulated by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) in accordance with the *Human Pathogens and Toxins Act* (HPTA), the *Human Pathogens and Toxins Regulations* (HPTR), the *Health of Animals Act*, and the *Health of Animals Regulations*.

The second edition of the CBS updates the biosafety standard originally published as Part I of the *Canadian Biosafety Standards and Guidelines* (CBSG), 1st Edition, 2013. The CBSG was developed to update and harmonize three existing Canadian biosafety standards and guidelines for the design, construction, and operation of facilities in which pathogens or toxins are handled or stored:

1. Human pathogens and toxins: *Laboratory Biosafety Guidelines*, 3rd Edition, 2004 (PHAC)
2. Terrestrial animal pathogens: *Containment Standards for Veterinary Facilities*, 1st Edition, 1996 (CFIA)
3. Prions: *Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents*, 1st Edition, 2005 (CFIA)

The CBS sets out the physical containment, operational practice, and performance and verification testing requirements for the safe handling or storing of human and terrestrial animal pathogens and toxins. The CBS updates many requirements to be more risk-, evidence-, and performance-based, as well as incorporating new information in the field of biocontainment engineering. In addition, the CBS includes several new requirements and information to support the full implementation of the HPTA and the HPTR. On December 1st, 2015, the HPTR comes into force and the CBS will come into effect and supersede the CBSG. The CBS will be used by the PHAC and the CFIA to verify the ongoing compliance of regulated facilities with the applicable legislation. This will support licence applications, renewals, animal pathogen import permit applications, and, where applicable, the facility certification (and recertification) of containment zones.

The Guidelines originally published as Part II of the CBSG have also been updated and are published in the *Canadian Biosafety Handbook* (CBH), 2nd Edition, 2015. The CBH is a companion document to the CBS that provides core information and guidance as to how the biosafety and biosecurity requirements outlined in the CBS can be achieved. The CBH systematically addresses the concepts required for the development and maintenance of a comprehensive risk-based biosafety management program. In some instances, however, best practices or risk mitigation strategies other than those described in the CBH may also be acceptable to achieve the requirements of the CBS.

The PHAC and the CFIA welcome comments, clarifications, and suggestions for incorporation into future editions of the CBS. To this end, please send information, with references (where applicable), for the continual improvement of the CBS to:

PHAC email: standards.normes@phac-aspc.gc.ca

CFIA email: standardsnormes@inspection.gc.ca

ABBREVIATIONS AND ACRONYMS

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Ag	Agriculture (i.e., CL2-Ag, CL3-Ag)
AIRS	Automated Import Reference System
ANSI	American National Standards Institute
ASME	American Society of Mechanical Engineers
BSC	Biological safety cabinet
BSO	Biological safety officer
CAN	National Standard of Canada
CBH	*Canadian Biosafety Handbook*
CBS	*Canadian Biosafety Standard*
CBSG	*Canadian Biosafety Standards and Guidelines*
CFIA	Canadian Food Inspection Agency
CL	Containment level (i.e., CL1, CL2, CL3, CL4)
CSA	Canadian Standards Association
CSFHAAP	*Containment Standards for Facilities Handling Aquatic Animal Pathogens*
CSFHPP	*Containment Standards for Facilities Handling Plant Pests*
ERP	Emergency response plan
HAA	*Health of Animals Act*
HAR	*Health of Animals Regulations*
HEPA	High efficiency particulate air
HPTA	*Human Pathogens and Toxins Act*

HPTA security clearance	*Human Pathogens and Toxins Act* security clearance
HPTR	*Human Pathogens and Toxins Regulations*
HVAC	Heating, ventilation, and air conditioning
IDA	Inward directional airflow
IEST	Institute of Environmental Sciences and Technology
in. w.g.	Inches of water gauge (unit of pressure; 1 in. w.g. = 250 Pa)
LA zone	Large animal containment zone
LRA	Local risk assessment
NSF	National Sanitation Foundation
PHAC	Public Health Agency of Canada
PM room	Post mortem room
PPE	Personal protective equipment
PSDS	Pathogen safety data sheet
RG	Risk group (i.e., RG1, RG2, RG3, RG4)
SA zone	Small animal containment zone
SMACNA	Sheet Metal and Air Conditioning Contractors National Association
SOP	Standard operating procedure
SSBA	Security sensitive biological agent
UPS	Uninterrupted power supply

GLOSSARY

GLOSSARY

It is important to note that while some of the definitions provided in the glossary are universally accepted, many of them were developed specifically for the *Canadian Biosafety Standard* (CBS); therefore, some definitions may not be applicable to facilities that fall outside of the scope of the CBS.

Accident	An unplanned event that results in injury, harm, or damage.
Administrative area	Dedicated room or adjoining rooms that are used for activities that do not involve infectious material and toxins. Administrative areas do not require any containment equipment, systems, or operational practices. Examples of administrative areas include offices, photocopy areas, and meeting/conference rooms.
Aerosol	A suspension of fine solid particles or liquid droplets in a gaseous medium (e.g., air) that can be created by any activity that imparts energy into a liquid/semi-liquid material.
Airborne pathogen	A pathogen that is capable of moving through or being carried by the air.
Airtight doors	Doors that are designed to allow no leakage of air (0%) under normal operating conditions and to withstand pressure decay testing and gaseous decontamination. Airtight doors can be achieved with inflatable or compression seals.
Animal cubicle	A room or space designed to house an animal (or animals) where the room itself serves as primary containment. These spaces are used to house large-sized animals (e.g., livestock, deer), or small-sized animals that are housed in open caging (i.e., not primary containment caging).
Animal pathogen	Any pathogen that causes disease in animals; including those derived from biotechnology. In the context of the *Canadian Biosafety Standard*, "animal pathogen" refers only to pathogens that cause disease in terrestrial animals; including those that infect avian and amphibian animals, but excluding those that cause disease in aquatic animals and invertebrates.

Animal pathogen import permit	A permit issued by the Public Health Agency of Canada or the Canadian Food Inspection Agency for the importation into Canada of: animal pathogens or toxins; animals, animal products, animal by-products, or other organisms carrying an animal pathogen or part of one; under Section 51(a) and (b) of the *Health of Animals Regulations*.
Animal room	A room designed to house animals in primary containment caging. These spaces are used to house only small-sized animals (e.g., mice, rats, rabbits).
Anteroom	A room, or series of rooms, inside the containment zone, used to separate "clean" areas from "dirty" areas (i.e., area with a lower risk of contamination from those with a higher risk of contamination), for personnel and animal entry/exit across the containment barrier, and for entry to/exit from animal rooms, animal cubicles, and post mortem rooms. The negative differential air pressures required in containment zones where inward directional airflow is provided can be more effectively maintained through the presence of an anteroom. An anteroom may also provide appropriate space at the entry/exit point(s) to don, doff and store dedicated containment zone clothing and additional personal protective equipment, as required.
Authorized personnel	Individuals who have been granted unsupervised access to the containment zone by the containment zone director, biological safety officer, or another individual to whom this responsibility has been assigned. This is dependent on completing training requirements and demonstrating proficiency in the standard operating procedures, as determined to be necessary by the facility.
Backdraft protection	A system that protects the air supply to the containment zone from contamination in the event of a reversal of air flow. High efficiency particulate air (HEPA) filters or isolation dampers are commonly used to prevent contamination from reaching areas of lower containment.
Backflow prevention	A system that protects the water supply to the containment zone from contamination. Many types of backflow devices also have test ports so that they can be checked to ensure that they are functioning properly.

Biocontainment	See "containment".
Biological material	Pathogenic and non-pathogenic microorganisms, proteins, and nucleic acids, as well as any biological matter that may contain microorganisms, proteins, nucleic acids, or parts thereof. Examples include, but are not limited to, bacteria, viruses, fungi, prions, toxins, genetically modified organisms, nucleic acids, tissue samples, diagnostic specimens, live vaccines, and isolates of a pathogen (e.g., pure culture, suspension, purified spores).
Biological safety cabinet (BSC)	A primary containment device that provides protection for personnel, the environment, and the product (depending on BSC class), when working with biological material.
Biological safety officer (BSO)	An individual designated for overseeing the facility's biosafety and biosecurity practices.
Biosafety	Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to infectious material and toxins, or their accidental release.
Biosafety Manual	A facility-specific manual that describes the core elements of a biosafety program (e.g., biosecurity plan, training, personal protective equipment).
Biosecurity	Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets (e.g., personnel, equipment, non-infectious material, and animals).
Biosecurity risk assessment	A risk assessment in which the pathogens, toxins, infectious material, and other related assets (e.g., equipment, animals, information) in possession are identified and prioritized, the threats and risks associated with these materials are defined, and appropriate mitigation strategies are determined to protect these materials against potential theft, misuse, diversion, or intentional release.

"Clean" change area	The designated space where dedicated personal protective equipment is donned when entering the containment zone, animal cubicle, or post mortem room. The "clean" change area is considered to be free from contamination when entry and exit procedures are routinely followed. In high containment zones, the "clean" change area is located outside the containment barrier.
Closed system	An apparatus or process system designed to contain biological material and prevent its release into the surrounding environment.
Commissioning	A process whereby a newly constructed containment zone, or a newly modified or renovated containment zone, is subjected to a series of performance and verification tests to ensure that the finished containment zone, including equipment and containment systems, will operate in accordance with the physical design intent and specifications and is ready to be put into operation, or resume activities involving pathogens and toxins, respectively.
Community	Encompasses both human (i.e., the public) and animal populations.
Containment	The combination of physical design parameters and operational practices that protect personnel, the immediate work environment, and the community from exposure to biological material. The term "biocontainment" is also used in this context.
Containment barrier	The boundary between "clean" and "dirty" areas (i.e., between the laboratory work areas, animal rooms, animal cubicles, or post mortem rooms, and outside of that containment area). Where inward directional airflow is provided, a physical containment barrier of air is established to protect against airborne or aerosolized infectious material or toxins from reaching the "clean" areas.
Containment level (CL)	Minimum physical containment and operational practice requirements for handling infectious material or toxins safely in laboratory, large scale production, and animal work environments. There are four containment levels ranging from a basic laboratory (containment level 1 [CL1]) to the highest level of containment (containment level 4 [CL4]).

Containment system	Dedicated equipment that functions to provide and maintain containment. This includes, but is not limited to, primary containment devices (e.g., biological safety cabinets), heating, ventilation, and air conditioning (HVAC) and control systems, and decontamination systems (e.g., autoclaves).
Containment zone	A physical area that meets the requirements for a specified containment level. A containment zone can be a single room (e.g., containment level 2 [CL2] laboratory), a series of co-located rooms (e.g., several non-adjoining but lockable CL2 laboratory work areas), or it can be comprised of several adjoining rooms (e.g., containment level 3 [CL3] suite with dedicated laboratory areas and separate animal rooms, or animal cubicles). Dedicated support areas, including anterooms (with showers and "clean" and "dirty" change areas, where required), are considered to be part of the containment zone.
Contamination	The undesired presence of infectious material or toxins on a surface (e.g., benchtop, hands, gloves) or within other materials (e.g., laboratory samples, cell cultures).
Controlled access system	A physical or electronic system designed to restrict access to authorized personnel only.
Controlled activities	Any of the following activities referred to in Section 7(1) of the *Human Pathogens and Toxins Act*: possessing, handling or using a human pathogen or toxin; producing a human pathogen or toxin; storing a human pathogen or toxin; permitting any person access to a human pathogen or toxin; transferring a human pathogen or toxin; importing or exporting a human pathogen or toxin; releasing or otherwise abandoning a human pathogen or toxin; or disposing of a human pathogen or toxin.
Critical door	Any door directly located on the containment barrier of a containment zone, animal cubicle, or post mortem room where inward directional airflow is required.

Culture	The *in vitro* propagation of microorganisms, tissue cells, or other living matter under controlled conditions (e.g., temperature, humidity, nutrients) to generate greater numbers or a higher concentration of the organisms/ cells. In the context of the *Canadian Biosafety Standard*, "cell culture" refers to cells derived from a human or animal source.
Decontamination	The process by which materials and surfaces are rendered safe to handle and reasonably free of microorganisms, toxins, or prions; this may be accomplished through disinfection, inactivation, or sterilization.
Decontamination technology	Equipment proven by validation to render materials safe to handle and reasonably free of microorganisms, toxins, or prions. Examples include autoclaves, incinerators, tissue digesters, and effluent decontamination systems.
Deep seal trap	A plumbing drain trap that has an effective head or depth that is sufficient to maintain a water seal, in accordance with air pressure differentials (i.e., water is neither siphoned into the room nor pushed through the trap). These traps have a water seal greater than 102 mm (4 inches) in depth, and a trap seal of 127 mm to 152 mm (5 to 6 inches).
"Dirty" change area	The designated space inside the containment barrier where contaminated personal protective equipment is doffed when exiting the containment zone, animal cubicle, or post mortem room. The "dirty" change area is considered to be contaminated or potentially contaminated during normal operations.
Disease	A disorder of structure or function in a living human or animal, or one of its parts, resulting from infection or intoxication. It is typically manifested by distinguishing signs and symptoms.
Disinfection	Process that eliminates most forms of living microorganisms; disinfection is much less lethal to infectious material than sterilization.
Dual-use potential	Qualities of a pathogen or toxin that allow it to be either used for legitimate scientific applications (e.g., commercial, medical, or research purposes), or intentionally misused as a biological weapon to cause disease (e.g., bioterrorism).

Dunk tank	A disinfectant-filled vessel located at or on the containment barrier that allows for the safe removal of material and samples from containment zones via surface decontamination achieved through immersion.
Effluent decontamination system	Equipment connected to the drain plumbing used to decontaminate, through heat or chemical means, the liquid waste (i.e., effluent) produced in a containment zone prior to release into sanitary sewers.
Emergency Response Plan (ERP)	A document outlining the actions to be taken and the parties responsible in emergency situations such as a spill, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, power failure, fire, explosion, or other emergency situations (e.g., flood, earthquake, hurricane).
Emerging animal disease	A new infectious disease resulting from the evolution or change of an existing pathogenic agent, a known infectious disease spreading to a new geographic area or population, or a previously unrecognized pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal health. Emerging animal disease pathogens are handled as non-indigenous animal pathogens due to the high risk of serious negative effects associated with these pathogens.
Exporting	The activity of shipping (e.g., transferring or transporting) pathogens, toxins, or other regulated infectious material from Canada to another country.
Exposure	Contact with, or close proximity to, infectious material or toxins that may result in infection or intoxication, respectively. Routes of exposure include inhalation, ingestion, inoculation, and absorption.
Exposure notification report	A tool used to notify and document preliminary information to the Public Health Agency of Canada of an exposure incident.
Exposure follow-up report	A tool used to report and document incident occurrence and investigation information for an exposure incident previously notified to the Public Health Agency of Canada.

Facility (plural: facilities)	Structures or buildings, or defined areas within structures or buildings, where infectious material or toxins are handled or stored. This could include individual research and diagnostic laboratories, large scale production areas, or animal housing zones. A facility could also be a suite or building containing more than one of these areas.
Facility certification	The formal acknowledgement from the Canadian Food Inspection Agency (CFIA) that a containment zone or facility where imported animal pathogens will be handled or stored complies with the physical containment, operational practice, and performance and verification testing requirements described in the *Canadian Biosafety Standard*. Recertification refers to the renewal of the facility certification issued by the CFIA following a streamlined review process.
Good microbiological laboratory practices	A basic laboratory code of practice applicable to all types of activities with biological material. These practices serve to protect workers and prevent contamination of the environment and the samples in use.
Gross contamination	The accumulation of organic material (e.g., bedding, feed, excrement, blood, and tissues) on a surface that can be removed by physical methods, such as scraping, brushing, and wiping.
Handling or storing	"Handling or storing" pathogens, toxins, or infectious material includes possessing, handling, using, producing, storing, permitting access to, transferring, importing, exporting, releasing, disposing of, or abandoning such material. This includes all controlled activities involving human pathogens and toxins specified in Section 7(1) of the *Human Pathogens and Toxins Act*.
High concentration	Infectious material or toxins that are concentrated to a degree that increases the risks associated with manipulating the material (i.e., increases the likelihood or consequences of exposure).
High containment zones	Containment zones (i.e., laboratory work areas, animal rooms and cubicles, post mortem rooms, areas for large scale production), including all dedicated support areas, in containment level 3 (CL3), containment level 3-Agriculture (CL3-Ag), and containment level 4 (CL4).

High efficiency particulate air (HEPA) filter	A device capable of filtering 99.97% of airborne particles 0.3 µm in diameter, the most penetrating particle size. Due to the effects of impaction, diffusion, and interception, HEPA filters are even more efficient at trapping and retaining particles that are either smaller or larger than 0.3 µm in diameter.
***Human Pathogens and Toxins Act* security clearance (HPTA security clearance)**	An authorization following verification of an individual's background and reliability status issued by the Public Health Agency of Canada under Section 34 of the *Human Pathogens and Toxins Act*.
Importing	The activity of bringing (e.g., transferring or transporting) pathogens, toxins, or other regulated infectious material into Canada from another country.
Incident	An event or occurrence with the potential of causing injury, harm, infection, intoxication, disease, or damage. Incidents can involve infectious material, infected animals, or toxins, including a spill, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, missing infectious material or toxins, unauthorized entry into the containment zone, power failure, fire, explosion, flood, or other crisis situations (e.g., earthquake, hurricane). Incidents include accidents and near misses.
Infectious material	Any isolate of a pathogen or any biological material that contains human or animal pathogens and, therefore, poses a risk to human or animal health.
In situ	Latin for "on site" or "in place"; describes a fixed location at which a procedure or experiment is conducted.
Interlock	A device or mechanism for coordinating the function of components (e.g., to prevent two doors being open simultaneously, or to ensure a supply fan shuts down in the event of an exhaust fan failure).

Intoxication	A substance-induced disorder or disease resulting in a symptomatic or asymptomatic condition, or other physiological change resulting from an exposure (i.e., ingestion, inhalation, inoculation, or absorption) to a toxin produced by or isolated from a microorganism. This includes a similar response from exposure to a synthetically produced microbial toxin.
Inventory	A list of (biological) assets associated with a containment zone identifying pathogens, toxins, and other infectious material in storage both inside and outside of the containment zone.
In vitro	Latin for "within glass"; describes experimentation involving components of a living organism within an artificial environment (e.g., manipulation of cells in petri dish), including activities involving cell lines or eggs.
In vivo	Latin for "within the living"; describes experimentation conducted within the whole living organism (e.g., studying the effect of antibiotic treatment in animal models).
Inward directional airflow (IDA)	Air that always flows from areas of lower containment or lower contamination risk to areas of higher containment or higher contamination risk, as the result of a negative air pressure differential within the containment zone created by a ventilation system.
Isolation damper	A shut-off valve used to seal off air supply and exhaust air ductwork to/from a containment zone, as well as plumbing vent lines to allow the decontamination of high efficiency particulate air (HEPA) filters. Isolation dampers also provide backdraft protection in the event of heating, ventilation, and air conditioning (HVAC) system failure or a reversal of airflow, and prevent puff-back in certain types of biological safety cabinets.
Laboratory	An area within a facility or the facility itself where biological material is handled for scientific or medical purposes.
Laboratory work area	Area inside a containment zone designed and equipped for *in vitro* research, diagnostics, and teaching purposes.

Large animal containment zone (LA zone)	Animal containment zone comprised of two or more co-located or adjoining rooms of equal containment level where animals are housed in animal cubicles (i.e., the room itself provides the primary containment). An LA zone may include, for example, large-sized animals, such as livestock or deer, housed in cubicles or, cubicles where small-sized animals, such as mice or raccoons, are housed in open caging (i.e., not primary containment caging). Post mortem rooms, where present, are considered to be part of an LA zone.
Large scale	Activities generally involving volumes of toxins or the *in vitro* culture of infectious material on a scale of 10 litres or greater. This could be a single vessel with a volume of 10 litres or greater, or based on the processes and pathogen used, could be multiple vessels with a total volume of 10 litres or greater. It is determined in consultation with the Public Health Agency of Canada and/or the Canadian Food Inspection Agency on a case-by-case basis, whether or not particular activities conducted in a containment zone are required to follow the increased or unique requirements for large scale production areas.
Large-sized animal	Refers to the physical size of the animal; large-sized animals are generally too large to be housed in primary containment caging, and are therefore housed in an animal cubicle. Examples include cows, horses, moose, deer, and sheep.
Large volume	A volume of infectious material or toxins that is sufficiently large to increase the risk associated with the manipulation of the material (i.e., increases the likelihood or consequences of exposure or release).
Licence	An authorization to conduct one or more controlled activities with human pathogens or toxins issued by the Public Health Agency of Canada under Section 18 of the *Human Pathogens and Toxins Act*.
Limited access	Access that is only permitted to authorized personnel and other authorized visitors through either operational means (e.g., having authorized personnel actively monitor and check all individuals entering a designated area) or through the use of a physical barrier (e.g., a controlled access system, such as key-locks or electronic access card).

Local risk assessment (LRA)	Site-specific risk assessment used to identify hazards based on the infectious material or toxins in use and the activities being performed. This analysis provides risk mitigation and risk management strategies to be incorporated into the physical containment design and operational practices of the facility.
Long-term storage	In the context of the *Canadian Biosafety Standard*, the possession of material (i.e., pathogens, toxins, and other regulated infectious material) beyond 30 days of receipt or creation.
Medical surveillance program	A program designed to prevent and detect personnel illness related to exposure to infectious material or toxins. The focus of the program is primarily preventive, but provides a response mechanism through which a potential infection or intoxication can be identified and treated before serious injury or disease occurs.
Microorganism	A cellular or non-cellular microbiological entity, capable of replication or transferring genetic material and that cannot be reasonably detected by the naked human eye. Microorganisms include bacteria, fungi, viruses, and parasites, and may be pathogenic or non-pathogenic in nature.
Movement	The action of moving (e.g., bringing, carrying, leading, relocating) people, material (including infectious material or toxins), or animals from one physical location to another physical location in the same building. This can include movement within the same containment zone, to a different containment zone, or to another location within the same building.
Non-indigenous animal pathogen	A pathogen that causes an animal disease listed in the World Organization for Animal Health's *OIE-Listed diseases, infections and infestations* (as amended from time to time) and that is exotic to Canada (i.e., foreign animal disease agents that are not present in Canada). These pathogens may have serious negative health effects to the Canadian animal population.
Open caging	Caging intended to restrict animals to an area (e.g., animal pens). This type of caging does not prevent the release of pathogens and toxins and, therefore, does not meet the requirements for primary containment caging.

Operational practice requirements	Administrative controls and procedures followed in a containment zone to protect personnel, the environment, and ultimately the community, from infectious material or toxins, as outlined in Chapter 4.
Overarching risk assessment	A broad risk assessment that supports the biosafety program as a whole and may encompass multiple containment zones within an institution or organization. Mitigation and management strategies reflect the type of biosafety program needed to protect personnel from exposure and to prevent the release of pathogens and toxins.
Pass-through chamber	Interlocked double-door compartment situated on a containment barrier that allows the safe movement of materials into and out of containment zones.
Pass-through technology	Equipment with double-door compartments situated on a containment barrier that allows the safe movement of materials into and out of the containment zone. Examples include double-door barrier autoclaves, pass-through chambers, dunk tanks, barrier cage washers, and feed chutes.
Pathogen	A microorganism, nucleic acid, or protein capable of causing disease or infection in humans or animals. Examples of human pathogens are listed in Schedules 2 to 4 and in Part 2 of Schedule 5 of the *Human Pathogens and Toxins Act*, but these are not exhaustive lists. Examples of animal pathogens can be found through the Automated Import Reference System on the Canadian Food Inspection Agency website.
Pathogen risk assessment	The determination of the risk group and appropriate physical containment and operational practice requirements needed to safely handle the infectious material or toxins in question.
Pathogenicity	The ability of a pathogen to cause disease in a human or animal host.
Performance and verification testing requirements	Performance and verification tests that are necessary to demonstrate compliance with the physical containment requirements, as outlined in Chapter 3 and, in some cases, the operational practice requirements, as outlined in Chapter 4. The performance and verification testing requirements are listed in Chapter 5.

Personal protective equipment (PPE)	Equipment and/or clothing worn by personnel to provide a barrier against infectious material or toxins, thereby minimizing the risk of exposure. PPE may include, but is not limited to, lab coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks, and respirators.
Physical containment requirements	Physical barriers in the form of engineering controls and facility design used to protect personnel, the environment, and ultimately the community, from pathogens or toxins, as outlined in Chapter 3.
Post mortem room (PM room)	A room within the containment zone where animal necropsies and dissections are conducted.
Pressure decay testing	A method of quantifying the leak rates of a sealed environment.
Primary containment	The first level of physical barriers designed to contain pathogens and toxins and prevent their release. This is accomplished by the provision of a device, equipment, or other physical structure situated between the infectious material or toxins and the individual, the work environment, or other areas within the containment zone. Examples include biological safety cabinets, glove boxes, and animal microisolators. In animal cubicles, the room itself provides primary containment, and personal protective equipment serves as primary protection against exposure.
Primary containment caging	Animal caging serving as a primary containment device to prevent the release of infectious material and toxins. Examples include ventilated filter-top cages and ventilated micro-isolator cage rack system, with or without high efficiency particulate air (HEPA) filters.
Primary containment device	Apparatus or equipment that is designed to prevent the release of infectious material or toxins and to provide primary containment (i.e., provide a physical barrier between the individual and/or the work environment and the biological material). Examples of primary containment devices include biological safety cabinets, isolators, centrifuges with sealable cups, process equipment, fermenters, microisolator cages, and ventilated cage racks.

Primary decontamination technology	The initial validated equipment or process used to decontaminate waste from the containment zone before disposal, incineration, or release to sanitary sewers. This serves to remove or inactivate infectious material or toxins through a process of disinfection, sterilization, or inactivation. This may be followed by a secondary decontamination process.
Prion	Small proteinaceous infectious particle generally considered to be responsible for causing a group of neurodegenerative diseases in humans and animals known as transmissible spongiform encephalopathies.
Process equipment	Specific equipment used to carry out a manufacturing procedure involving biological material. This term is generally used to describe equipment used in large scale processes (e.g., industrial fermentation equipment).
Program intent	A description of the planned work to be performed in a containment zone. This includes, but is not limited to, the scope of work (e.g., diagnostic, teaching, research, large scale production, *in vitro* work, *in vivo* work), a list of pathogens, toxins, and other regulated infectious material to be handled or stored, a list of animal species to be involved in *in vivo* work with pathogens and toxins in the zone, and a list of procedures that may create aerosols.
Puff-back	The reversal of airflow from the face of a Class II type B2 biological safety cabinet due to failure of the exhaust fan.
Release	The discharge of infectious material or toxins from a containment system.
Representative load	A simulation batch of materials of a similar type (e.g., gloves, plastics, liquids) and quantity used to validate a decontamination method for routine loads.
Restricted access	Access that is strictly controlled to authorized personnel only by means of a physical barrier (i.e., a controlled access device or system, such as an electronic access card, access code, etc.).

Risk	The probability of an undesirable event (e.g., accident, incident, breach of containment) occurring and the consequences of that event.
Risk group (RG)	The classification of biological material based on its inherent characteristics, including pathogenicity, virulence, risk of spread, and availability of effective prophylactic or therapeutic treatments, that describes the risk to the health of individuals and the public as well as the health of animals and the animal population.
Risk management plan	A plan that provides the foundation and organizational arrangements for designing, implementing, monitoring, reviewing, and continually improving risk management throughout the organization.
Scientific research	As defined in Section 1 of the *Human Pathogens and Toxins Regulations*: the following types of systematic investigation or research that are carried out in a field of science or technology by means of controlled activities: a) basic research, when the controlled activities are conducted for the advancement of scientific knowledge without a specific practical application; b) applied research, when the controlled activities are conducted for the advancement of scientific knowledge with a specific practical application; c) experimental development, when the controlled activities are conducted to achieve scientific or technological advancement for the purpose of creating new – or improving existing – materials, products, processes, or devices.
Sealable doors	Doors that are designed to allow leakage of air under normal operating conditions yet are capable of being sealed to withstand pressure decay testing and gaseous decontamination (e.g., three-sided or four-sided gasket, four-sided door jamb).
Security barrier	A physical obstruction designed to prevent access to pathogens, infectious material, toxins, or other related assets by unauthorized personnel (e.g., locked doors, controlled access systems, or padlocked storage equipment) that increases the security of a containment zone by restricting access to authorized personnel only.

Security sensitive biological agents (SSBAs)	The subset of human pathogens and toxins that have been determined to pose an increased biosecurity risk due to their potential for use as a biological weapon. SSBAs are identified as prescribed human pathogens and toxins by Section 10 of the *Human Pathogens and Toxins Regulations*. This means all Risk Group 3 and Risk Group 4 human pathogens that are in the *List of Human and Animal Pathogens for Export Control*, published by the Australia Group, as amended from time to time, with the exception of Duvenhage virus, Rabies virus and all other members of the Lyssavirus genus, and Vesicular stomatitis virus; as well as all toxins listed in Schedule 1 of the *Human Pathogens and Toxins Act* that are listed on the *List of Human and Animal Pathogens for Export Control* when in a quantity greater than that specified in Section 10(2) of the *Human Pathogens and Toxins Regulations*.
Small-sized animal	Refers to the physical size of the animal; small-sized animals are small enough to be housed in primary containment caging. Examples include rodents, rabbits, ferrets, chickens, and non-human primates. Small-sized animals may also be housed in an animal cubicle (e.g., when open caging is used).
Small animal containment zone (SA zone)	Animal containment zone comprised of one or several co-located or adjoining rooms of equal containment level where animals are housed in animal rooms inside primary containment caging (e.g., microisolators). An SA zone may contain, for example, mice, rats, rabbits, ferrets, or non-human primates, provided that they are housed in primary containment caging.
Standard operating procedure (SOP)	A document that standardizes safe work practices and procedures for activities with infectious material and toxins in a containment zone, as determined by a local risk assessment.
Sterilization	Process that completely eliminates all living microorganisms, including bacterial spores.
Strict animal pathogen	A pathogen that causes disease exclusively in animals (i.e., not capable of causing disease in humans).

(Microbial) Toxin	A poisonous substance that is produced or derived from a microorganism and can lead to adverse health effects in humans or animals. Human toxins are listed in Schedule 1 and Part 1 of Schedule 5 in the *Human Pathogens and Toxins Act*.
Terrestrial animal pathogen	A pathogen that causes diseases in terrestrial animals, including avian and amphibian animals, but excluding aquatic animals and invertebrates.
Training needs assessment	An evaluation performed to identify the current and future training needs of the facility (organization, containment zone) and to identify gaps in the current training program.
Transfer	A change in possession of pathogens, toxins, or other regulated infectious material between individuals from the same or different facilities (i.e., the movement from the place or places specified in the licence or animal pathogen import permit to any other place).
Transportation	The act of transporting (e.g., shipping or conveyance) infectious material or toxins to another building or location (i.e., different address), within Canada or abroad, in accordance with the *Transportation of Dangerous Goods Act* and *Regulations*.
Trigger quantity	The minimum quantity above which a toxin regulated by the *Human Pathogens and Toxins Act* is considered a "prescribed toxin" and, therefore, a security sensitive biological agent, as described by Section 10(2) of the *Human Pathogens and Toxins Regulations*.
Validation	The act of confirming that a method achieves its objective by observing that specific parameters have been met (e.g., using biological indicators to confirm that a given autoclave cycle can decontaminate a representative load of waste). Validation infers that a method is suitable for its intended purpose.

Ventilated cage changing station	Equipment specifically designed to change bedding and other contents from animal cages that: a) directs the air away from the user into the interior of the unit at a sufficient velocity to protect the user from potential exposure to any infectious material or toxins; and b) filters the exhaust air prior to release from the unit, thereby preventing the potential release of infectious material or toxins into the environment.
Verification	The routine monitoring of equipment and processes to ensure continued efficacy between validations. This includes comparing the accuracy of a piece of equipment to an applicable standard or standard operating procedure (e.g., testing of a Class I biological safety cabinet in accordance with the manufacturer specifications).
Virulence	The degree or severity of a disease caused by a pathogen.
Waste	Any solid or liquid material generated by a facility for disposal.
Zoonoses	Diseases that are transmissible between living animals and humans. Zoonoses include anthropozoonoses (i.e., diseases transmitted from animals to humans) and zooanthropoposes, also known as reverse zoonoses (i.e., diseases transmitted from humans to animals).
Zoonotic pathogen	A pathogen that causes disease in humans and animals, and that can be transmitted from animals to humans and vice versa (i.e., zoonoses). They are considered both human and animal pathogens.

NORMATIVE REFERENCES

NORMATIVE REFERENCES

American National Standards Institute (ANSI) / Sheet Metal and Air Conditioning Contractors National Association, Inc. (SMACNA)

ANSI/SMACNA 016-2012, HVAC Air Duct Leakage Test Manual, 2nd Edition.

American Society of Mechanical Engineers (ASME)

ASME AG-1-2012, Code on Nuclear Air and Gas Treatment.

ASME N511-2007, In-service Testing of Nuclear Air Treatment, Heating, Ventilating, and Air-Conditioning Systems.

Institute of Environmental Sciences and Technology (IEST)

IEST RP-CC001.5, HEPA and ULPA Filters.

IEST RP-CC034, HEPA and ULPA Filter Leak Tests.

National Sanitation Foundation (NSF)/ American National Standards Institute (ANSI)

NSF/ANSI 49-2012, Biosafety Cabinetry: Design, Construction, Performance, and Field Certification.

National Standard of Canada (CAN)/ Canadian Standards Association (CSA)

CAN/CSA B64.10-11/B64.10.1-11, Selection and Installation of Backflow Preventers/Maintenance and Field Testing of Backflow Preventers.

CAN/CSA Z180.1-13 (R2013), Compressed Breathing Air and Systems.

CHAPTER 1

INTRODUCTION

1.1 Scope

The **handling or storing** of **pathogens** or **toxins** necessitates an awareness and application of **biosafety** and **biosecurity** practices among personnel in **laboratories** and other **containment zones** where work with pathogens, toxins, or infected animals is conducted. The **release** of human and **animal pathogens** and toxins from laboratories or other containment zones may pose a **risk** to public health, animal health, or both. Personnel can minimize the risks associated with pathogens or toxins through the application of appropriate biosafety and **biocontainment** principles and practices.

In Canada, **facilities** where human pathogens or toxins are handled or stored, such as public health laboratories, teaching and research laboratories, diagnostic laboratories in hospitals, and vaccine production plants, are regulated under the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations* (HPTR). Canadian facilities that import animal pathogens, or animals, animal products or by-products (e.g., tissue, serum), or other substances that may carry an animal pathogen or parts thereof are regulated by the *Health of Animals Act* (HAA) and the *Health of Animals Regulations* (HAR). **Zoonotic pathogens**, capable of causing **disease** in human and animal hosts, that are imported into Canada are regulated by the HPTA, HPTR, HAA, and HAR. The *Canadian Biosafety Standard* (CBS), 2nd Edition, 2015 describes the minimum requirements for containment zones in a regulated facility; this includes facilities that have been issued a **licence** under the HPTA and HPTR, as well as facilities that have been issued an **animal pathogen import permit** under the HAA and HAR. For facilities exempt from the licence requirements under the HPTA and the HPTR and not **importing** under the HAA and the HAR, it is considered best practice to demonstrate, by following the CBS requirements, that all reasonable precautions have been taken to protect the health and safety of the public against the risks associated with the materials in their possession.

The CBS sets out the **physical containment requirements**, **operational practice requirements**, and **performance and verification testing requirements** for facilities where human or **terrestrial animal pathogens** or toxins are handled or stored. Terrestrial animal pathogens cause disease in terrestrial animals, including avian and amphibian animals, but exclude pathogens of aquatic animals and invertebrates. Facilities in Canada where imported aquatic animal pathogens are handled or stored must comply with the Canadian Food Inspection Agency's (CFIA's) *Containment Standards for Facilities Handling Aquatic Animal Pathogens* (CSFHAAP), 1st Edition, 2010. In situations where facilities handle or store pathogens that cause disease in aquatic animals and either humans or terrestrial animals, the facility is required to adhere to both the CBS as well as the CSFHAAP. Likewise, facilities in Canada where imported plant pests are handled or stored must comply with the CFIA's *Containment Standards for Facilities Handling Plant Pests* (CSFHPP), 1st Edition, 2007. Compliance with both the CBS as well as the CSFHPP is required in the event that an imported plant pest is also capable of causing disease in either humans or terrestrial animals.

1.2 Regulatory Authorities

The Public Health Agency of Canada (PHAC) is the national authority on biosafety and biosecurity for human pathogens and toxins. The PHAC is responsible for the regulation of human pathogens and toxins under the authority of the HPTA and the HPTR and the importation or **transfer** of pure **cultures** of terrestrial animal pathogens and toxins, with the exception of **non-indigenous animal pathogens** and pathogens causing **emerging animal disease**, under the authority of the HAA and the HAR.

The Canadian Food Inspection Agency (CFIA) is the national authority on biosafety and biosecurity for foreign animal diseases and emerging animal diseases. The CFIA is responsible for the regulation of the importation or transfer of pure cultures of non-indigenous animal pathogens and emerging animal disease pathogens, as well as animals, animal products, and animal by-products that contain a terrestrial animal pathogen, under the authority of the HAA and HAR. In addition, the CFIA is responsible for the regulation of the importation or transfer of aquatic animal pathogens and plant pests. Please contact the CFIA for further details regarding requirements for these pathogens.

On December 1st, 2015, the HPTR comes into force and the CBS will come into effect and supersede the *Canadian Biosafety Standards and Guidelines* (CBSG), 1st Edition, 2013. The CBS will be used by the PHAC and the CFIA to verify the ongoing compliance of regulated facilities. Compliance with the physical containment, operational practice, and performance and verification testing requirements, respectively described in Chapters 3, 4, and 5 of the CBS, will help prevent the inadvertent release of pathogens or toxins, which could potentially pose significant risks to the health of humans or animals, the environment, or the economy.

In some instances, facilities may need to be upgraded or renovated to meet some of the physical containment requirements outlined in Chapter 3. As per the current compliance and enforcement program, the PHAC and the CFIA will review non-compliance items on a case-by-case basis. Regulated parties are encouraged to discuss non-compliance items with the relevant agency (or agencies) to determine a timeframe for compliance based on the level of risk and the risk mitigation strategies in place or to determine if alternative mitigation strategies can be implemented for these items.

For more information about the biosafety and biosecurity work of the PHAC, an e-mail can be sent to biosafety.biosecurite@phac-aspc.gc.ca, or visit the PHAC website (www.publichealth.gc.ca/pathogens). For more information about the work of the CFIA, an email can be sent to biocon@inspection.gc.ca, or visit the CFIA website (www.inspection.gc.ca/english/sci/bio/bioe.shtml).

1.3 Legislative and Regulatory Requirements for Human Pathogens and Toxins

Under the HPTA and the HPTR, facilities conducting **controlled activities** involving human pathogens or toxins have specific requirements in addition to the requirements described in the CBS. A summary of these requirements is described in Tables 1-1 and 1-2 below; this, however, is not an exhaustive list, and persons conducting controlled activities with human pathogens or toxins are to refer to the specific sections of the HPTA or HPTR for a complete understanding of the requirements. It remains the responsibility of the facility (regulated party) to understand their obligations under both the HPTA and HPTR, in addition to the applicable requirements set out in the CBS and their conditions of licence. The *Human Pathogens Importation Regulations* will be repealed when the HPTR comes into effect, and the licensing program outlined in the HPTR will replace the need for human pathogen and toxin import permits.

Table 1-1. Summary of the key legislative and regulatory requirements for all facilities that fall under the scope of the *Human Pathogens and Toxins Act*.

Key Requirements that apply to all facilities under the scope of the HPTA (i.e., licensed and licence-exempted facilities)	Corresponding Section(s) of HPTA/HPTR
Every person who knowingly conducts controlled activities with human pathogens and toxins must take all reasonable precautions to protect the health and safety of the public.	HPTA 6
Any activity with the human pathogens or toxins listed in Schedule 5 of the HPTA is strictly prohibited.	HPTA 8
Unless otherwise exempted, a licence must be obtained from the PHAC to authorize any of the following controlled activities: • possessing, handling, or using a human pathogen or toxin; • producing a human pathogen or toxin; • storing a human pathogen or toxin; • permitting any person access to a human pathogen or toxin; • transferring a human pathogen or toxin; • importing or **exporting** a human pathogen or toxin; • releasing or otherwise abandoning a human pathogen or toxin; or • disposing of a human pathogen or toxin.	HPTA 7(1)

Table 1-2. Summary of the legislative and regulatory requirements applicable only to licence holders.

Key Requirements that apply to all licensed facilities	Corresponding Section(s) of HPTA/HPTR
Licence Requirements	
A licence applicant who intends to carry out **scientific research** must develop a plan that sets out how they will administratively manage and control biosafety and biosecurity risks during the term of the licence (i.e., **risk management plan**), before the licence can be issued.	HPTR 3
Licence applicants are required to designate a **biological safety officer** (BSO) before a licence may be issued.	HPTA 36(1)
Conditions of Licence	
Licences are subject to conditions, and a licence holder and all persons conducting controlled activities under a licence must comply with those conditions.	HPTA 18(4) HPTA 18(7)
Licence holders are required to communicate all licence conditions to everyone conducting activities under that licence.	HPTA 18(6)

Key Requirements that apply to all licensed facilities	Corresponding Section(s) of HPTA/HPTR
The following conditions apply to every licence: 1. licence holders and persons conducting controlled activities authorized under the licence must not obstruct a BSO when the BSO is exercising their powers or carrying out their functions; 2. the BSO must be notified before arrangements are made to do the following: • import a human pathogen or toxin; • receive a human pathogen or toxin from another facility; • transfer a human pathogen or toxin to another facility; 3. persons transferring human pathogens or toxins within Canada must take reasonable care to satisfy themselves that the intended recipient is licensed to work with the agent or otherwise exempted from the requirement to hold a licence; 4. persons exporting human pathogens and toxins outside of Canada must take reasonable care to satisfy themselves that the intended recipient will follow applicable biosafety and biosecurity standards and policies in the foreign jurisdiction; 5. intended recipients of human pathogens and toxins must make reasonable efforts to locate human pathogens and toxins that are not received within a reasonable time of when they are expected to be received, and the BSO must be notified of the situation without delay; and 6. persons who discover that they are inadvertently in possession of a human pathogen or toxin that they are not authorized to possess and that is not a Schedule 5 agent must immediately notify the BSO, ensure that the human pathogen or toxin is handled and stored appropriately, and dispose of it or transfer it to a licence holder authorized to conduct controlled activities with that pathogen or toxin within 30 days.	HPTR 4(1)
The following additional condition applies to every licence that authorizes controlled activities with **security sensitive biological agents** (SSBAs): 1. intended recipients of SSBAs who do not receive them within 24 hours after the date and time they were expected to be received must make reasonable efforts to locate the SSBAs, inform the BSO without delay, and provide the BSO with any relevant information.	HPTR 4(2)

Key Requirements that apply to all licensed facilities	Corresponding Section(s) of HPTA/HPTR
Any licence conditions that are specific to a particular licence are set out on the licence itself. Compliance with the applicable requirements in the CBS will be included as a licence-specific condition.	HPTA 18(4)
Biological Safety Officer Requirements	
BSOs must have the following minimum qualifications: 1. knowledge of microbiology appropriate to the risks associated with the controlled activities being conducted, attained through a combination of education, training, and experience; 2. knowledge of the HPTA, the HPTR, and any applicable federal or provincial legislation; and 3. knowledge of applicable biosafety and biosecurity policies, standards, and practices appropriate to the risks associated with the controlled activities being conducted.	HPTA 36(3) HPTR 8
BSOs have the following functions: 1. verifying the accuracy and completeness of licence applications; 2. communicating with the PHAC on behalf of the licence holder; 3. promoting and monitoring compliance, including but not limited to: • arranging for and documenting training related to biosafety and biosecurity policies, standards, and practices; • notifying the PHAC of any inadvertent possession of human pathogens and toxins or of any SSBAs not received as expected; • conducting periodic internal inspections and biosafety audits and reporting findings to the licence holder; • informing the licence holder of any non-compliance by a person conducting activities under the licence that is not resolved after that person has been made aware of it; 4. assisting in the development and maintenance of the **Biosafety Manual** and **standard operating procedures** (SOPs) related to biosafety and biosecurity; and 5. assisting with internal investigations of **incidents**.	HPTA 36(5) HPTR 9(1)

Key Requirements that apply to all licensed facilities	Corresponding Section(s) of HPTA/HPTR
BSOs have the following power: • may require any person who conducts controlled activities under the licence to provide them with any records that are necessary to assist them in carrying out their functions.	HPTA 36(5) HPTR 9(2)
***Human Pathogens and Toxins Act* Security Clearance Requirements**	
Persons are prohibited from entering a part of a facility in which controlled activities with SSBAs are authorized unless they hold a valid ***Human Pathogens and Toxins Act* security clearance** (HPTA security clearance) issued by the PHAC, or are accompanied and supervised by a person who holds an HPTA security clearance. This prohibition does not apply if there are no SSBAs in that part of a facility, or if any SSBAs that are present are locked up and inaccessible.	HPTA 33 HPTR 28
A holder of an HPTA security clearance may only accompany and supervise one person who does not hold a clearance at any one time (1 to 1 ratio), and must be in the same room and monitor their activities at all times.	HPTR 23
Persons who do not hold an HPTA security clearance may not be accompanied and supervised if their HPTA security clearance is suspended, or if they have previously been refused an HPTA security clearance or had one revoked (and a new one has not been issued since that time).	HPTR 24
As part of the HPTA security clearance application process, applicants will need to submit a statement signed by a licence holder certifying that they require an HPTA security clearance for a particular part or parts of a facility.	HPTR 12(1)(m)
The HPTA security clearance is transferable between facilities, but the holder of an HPTA security clearance must provide a new statement to the PHAC, signed by the licence holder, certifying that they require an HPTA security clearance before an HPTA security clearance holder enters a part of a facility that was not authorized by their existing HPTA security clearance.	HPTR 18

Key Requirements that apply to all licensed facilities	Corresponding Section(s) of HPTA/HPTR
Reporting Requirements	
The licence holder and the BSO must be notified whenever the licence holder or any person who is conducting controlled activities authorized under a licence intends to increase the **virulence**, **pathogenicity**, communicability of a human pathogen, or the resistance of a human pathogen to preventive or therapeutic treatments, or to increase the toxicity of a toxin.	HPTR 5
Every person conducting controlled activities under authority of a licence must inform the licence holder and the BSO without delay of any inadvertent release or production of a human pathogen or toxin, of any incident involving a human pathogen or toxin that has caused, or may have caused, disease in an individual, or if a pathogen or toxin has been stolen or is otherwise missing.	HPTA 15 HPTR 4
Notification must be provided to the PHAC without delay in the following circumstances:	
• when a licence holder has reason to believe that a human pathogen or toxin has been released inadvertently from a facility;	HPTA 12(1)
• when a human pathogen or toxin that a person is not authorized to possess is inadvertently produced or otherwise comes into their possession;	HPTA 12(2); HPTR 9(1)(c)(ii)
• when an incident involving a human pathogen or toxin has caused, or may have caused, disease in an individual;	HPTA 13
• when there is reason to believe that a human pathogen or toxin has been stolen or is otherwise missing;	HPTA 14
• when a licence holder decides to prohibit the holder of an HPTA security clearance from accessing a licensed facility, including the reasons for that decision;	HPTA 32; HPTR 7
• when the designated BSO has changed;	HPTA 36(6)
• where an SSBA is not received within 24 hours of the date and time when it was expected to be received; and	HPTR 9(1)(c)(iii)
• where the holder of an HPTA security clearance is convicted of a criminal offence.	HPTR 19

Key Requirements that apply to all licensed facilities	Corresponding Section(s) of HPTA/HPTR
Notification must be provided to the PHAC in the following circumstances: • <u>before</u> making any of the following changes, if they could affect biocontainment, where controlled activities with **Risk Group** 3 or 4 human pathogens or SSBA toxins are conducted: o changes to the physical structure of their facility; o changes to any equipment; or o changes to their SOPs; and • <u>within a reasonable time</u> of a licence holder making a name change.	HPTR 6(1) HPTR 6(2)
Records and Documentation Requirements	
Licence holders are required to keep a list of all persons authorized to access a licensed facility, including persons holding HPTA security clearances and visitors.	HPTA 31
Licence holders are required to keep a record of the full name of every person who enters, under accompaniment and supervision, a facility where SSBAs are present, including the date and the full name of the person who accompanied and supervised them.	HPTR 25

1.4 Legislative and Regulatory Requirements for Animal Pathogens, Toxins, and other Regulated Infectious Material

Under the HAA and the HAR, Canadian facilities that import animal pathogens or part of one that retains its pathogenicity (e.g., toxins), or animals, animal products (e.g., cream, milk, eggs) or by-products (e.g., blood, serum, tissues), or other substances that may carry an animal pathogen or part of one that retains its pathogenicity have specific requirements in addition to the requirements described in the CBS. A summary of these requirements is described in Table 1-3 below; this, however, is not an exhaustive list, and persons applying for an animal pathogen import permit are to refer to the specific sections of the HAA or HAR for a complete understanding of the requirements. It remains the responsibility of the facility (importer) to understand their obligations under both the HAA and HAR, in addition to the applicable requirements set out in the CBS and their conditions of import permit.

Table 1-3. Summary of the key legislative and regulatory requirements for importers under the scope of the *Health of Animals Act* and the *Health of Animals Regulations*.

Key Requirements that apply to importers under the HAA and HAR	Corresponding Section(s) of HAA/HAR
The importation of any animal or other thing into Canada is prohibited and subject to regulation under the HAR for the purpose of preventing a disease or toxic substance from being introduced into or spread within Canada.	HAA 14
No person shall possess or dispose of an animal or thing that the person knows was imported in contravention of the HAA or the regulations.	HAA 15(1)
An animal pathogen import permit must be obtained from the PHAC or the CFIA prior to the importation of the following: • an animal pathogen or part of one that retains its pathogenicity (e.g., toxin); and • an animal, animal product, animal by-product, or other organism carrying an animal pathogen or part of one that retains its pathogenicity (e.g., toxin).	HAR 51(a) and (b)

Key Requirements that apply to importers under the HAA and HAR	Corresponding Section(s) of HAA/HAR
An animal pathogen import permit may be issued by the PHAC or the CFIA, provided that the relevant agency is satisfied that the activity for which the permit is issued would not, or would not be likely to, result in the introduction into Canada, the introduction into another country from Canada, or the spread within Canada of a vector, disease, or toxic substance.	HAR 160(1.1)
Conditions of Animal Pathogen Importation	
Where any animal pathogen or part of one that retains its pathogenicity (e.g., toxin) referred to in Section 51 is imported into Canada under a permit, no person shall: • move the imported pathogen or part of one that retains its pathogenicity (e.g., toxin) from the place or places specified in the permit to any other place, except under and in accordance with that permit or another permit issued for that purpose; or • introduce into an animal the imported pathogen or part of one that retains its pathogenicity (e.g., toxin) except under and in accordance with that permit or another permit issued for that purpose.	HAR 51.1
Any animal pathogen import permit issued under the HAR shall contain such conditions as the PHAC and/or the CFIA consider advisable to prevent the introduction of communicable disease into Canada or into any other country from Canada and the spread of communicable disease within Canada.	HAR 160(1.1)(2)
Every person to whom a permit is issued under the HAR shall comply with the conditions contained in the animal pathogen import permit.	HAR 160.1

CHAPTER 2

HOW TO USE THE *CANADIAN BIOSAFETY STANDARD*

CHAPTER 2 – HOW TO USE THE *CANADIAN BIOSAFETY STANDARD*

The *Canadian Biosafety Standard* (CBS) describes, according to **containment level**, the **physical containment requirements**, **operational practice requirements**, and **performance and verification testing requirements** for **facilities** where **pathogens**, **toxins**, or other regulated **infectious material** are handled or stored. In the context of the CBS, "**handling or storing**" pathogens or toxins includes possessing, handling, using, producing, storing, permitting access to, transferring, **importing**, **exporting**, releasing, disposing of, or abandoning such material.

2.1 Abbreviations, Definitions, and References

The CBS includes a detailed list of all abbreviations and acronyms used throughout; this list is located at the beginning of the document. Each abbreviation or acronym is spelled out upon first use in a chapter and, in Chapters 3, 4, and 5, in each section or matrix, with the abbreviation immediately following in brackets; the abbreviation is used exclusively throughout the remainder of the chapter or matrix.

The CBS contains a comprehensive glossary of definitions for technical terms, located at the beginning of the document; words defined in the glossary appear in **bold type** upon first use in each chapter and, in Chapters 3, 4, and 5, in each section or matrix. The terminology used in the CBS is to be interpreted according to the corresponding definitions provided in the glossary.

The CBS includes a list of normative references at the beginning of the document, providing a summary of all external standards cited in the text. Except where information from an external standard is directly incorporated into the CBS, external standards are referenced by number only, and users are to refer to the most current version available. A full list of the external standards and other documents that are referenced in the CBS is provided at the end of the document.

2.2 Containment Levels and Containment Zones

Containment level refers to the minimum physical containment and operational practices required for a **containment zone** where infectious material or toxins can be safely handled. The CBS describes the three containment levels regulated by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA), ranging from the lowest level permitted to work with pathogens, toxins, and other regulated infectious material (containment level 2 [CL2]) to the highest level of containment (containment level 4 [CL4]). A containment zone itself is a physical area that meets the requirements for a specified containment level. This can be a single room (e.g., a **laboratory**) or a series of co-located rooms (e.g., several non-adjoining but lockable CL2 **laboratory work areas**), or it can be comprised of several adjoining rooms of the same containment level (e.g., containment level 3 [CL3] suite comprised of dedicated laboratory work area and support areas, such as

anterooms, change rooms, storage rooms, preparation areas, wash up rooms, centralized autoclave room). A containment zone may include one or more work areas of different types (i.e., laboratory work area, **large scale** production area, animal work areas), as long as they are of the same containment level.

2.3 Working with Human and Animal Pathogens and Toxins

2.3.1 Pathogens and Risk Groups

A pathogen is a **microorganism**, nucleic acid, or protein capable of causing **disease** in humans or terrestrial animals. This can include bacteria, viruses, fungi, parasites, **prions**, recombinant DNA, genetically modified microorganisms, viral vectors, and synthetic biology products. Human pathogens are capable of causing disease in humans; **animal pathogens** cause disease in animals. For the purposes of the CBS, the term "animal pathogens" from this point forward refers only to pathogens that cause disease in terrestrial animals, including avian and amphibian animals. **Zoonotic pathogens** are pathogens that cause diseases in humans and terrestrial animals and that can be transmitted from animals to humans or vice versa (i.e., **zoonoses**), and are, therefore, considered as both human and animal pathogens. In the context of the CBS, any isolate of a pathogen or any **biological material** that contains human or animal pathogens is referred to as "infectious material".

The following definitions provide the **risk group** categorization for both human and animal pathogens based on the **risk** to the individual/animal and the risk to the **community**. Examples of human pathogens are listed in Schedules 2 to 4 and in Part 2 of Schedule 5 of the *Human Pathogens and Toxins Act* (HPTA), but these are not exhaustive lists. Examples of animal pathogens can be found on the CFIA website.

2.3.1.1 Risk Group 1 (RG1; low individual and community risk)

A microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease; or b) capable of causing human or animal disease, but unlikely to do so. RG1 organisms capable of causing disease are considered pathogens that pose a low risk to the health of individuals or animals, and a low risk to public health and the animal population. RG1 pathogens can be opportunistic and may pose a threat to immunocompromised individuals. Neither of the RG1 subsets is regulated by the PHAC or the CFIA due to the low risk to public health and the animal population.

2.3.1.2 Risk Group 2 (RG2; moderate individual risk, low community risk)

A pathogen or toxin that poses a moderate risk to the health of individuals or animals, and a low risk to public health and the animal population. These pathogens are able to cause serious disease in a human or animal but are unlikely to do so. Effective treatment and preventive measures are available and the risk of spread of diseases caused by these pathogens is low. Examples of RG2 human pathogens are included in Schedule 2 of the HPTA.

2.3.1.3 Risk Group 3 (RG3; high individual risk, low community risk)

A pathogen that poses a high risk to the health of individuals or animals, and a low risk to public health. These pathogens are likely to cause serious disease in a human or animal. Effective treatment and preventive measures are usually available and the risk of spread of disease caused by these pathogens is low for the public. The risk of spread to the animal population, however, can range from low to high depending on the pathogen. Examples of RG3 human pathogens are included in Schedule 3 of the HPTA.

2.3.1.4 Risk Group 4 (RG4; high individual risk, high community risk)

A pathogen that poses a high risk to the health of individuals or animals and a high risk to public health. These pathogens are likely to cause serious disease in a human or animal which can often lead to death. Effective treatment and preventive measures are not usually available and the risk of spread of disease caused by these pathogens is high for the public. The risk of spread of disease to the animal population, however, ranges from low to high depending on the pathogen. Examples of RG4 human pathogens are included in Schedule 4 of the HPTA.

2.3.2 Determining the Containment Level

In general, the containment level and risk group of the pathogen are the same (e.g., RG2 pathogens are handled at CL2); however, there are exceptions, and not all biological material will fall perfectly into a given risk group or containment level following a risk assessment. In some cases, there is a higher or unique level of risk associated when handling certain pathogens (e.g., **non-indigenous animal pathogens** or prions) or with certain types of work (e.g., ***in vivo*** work or ***in vitro*** work involving large scale volumes of pure or concentrated **cultures** of pathogens). In other cases, biological material (e.g., tissues, diagnostic specimens) may harbour pathogens, toxins, prions, or modified components of a pathogen, in which case, a site-specific **local risk assessment** (LRA) is critical to evaluate and determine which work-specific operational practices and mitigation strategies are to be implemented to achieve the appropriate level of precaution.

It is very difficult to develop a comprehensive list of human and animal pathogens due to the emergence of new pathogens and the ongoing research into the characteristics of existing pathogens. Well-characterized pathogens that have had a **pathogen risk assessment** completed by the PHAC or the CFIA have been assigned an appropriate risk group and containment level. Risk assessments on well-characterized human and zoonotic pathogens have been developed into technical documents by the PHAC known as Pathogen Safety Data Sheets (PSDSs) that describe the hazardous properties of pathogens and recommendations for their safe handling and are readily available on the PHAC website. Fact Sheets for federally reportable diseases affecting terrestrial animals in Canada have been developed by the CFIA and are also readily available on the CFIA website. The appropriate containment level and any additional requirements to work with certain animal pathogens (e.g., non-indigenous animal pathogens and **emerging animal disease** pathogens) are determined by the CFIA through a pathogen risk assessment and containment level assessment.

2.3.3 Toxins

Biological toxins are poisonous substances that are a natural product of the metabolic activities of certain microorganisms, plants, and animal species. Unlike pathogens, toxins are non-infectious and unable to propagate when isolated from the parental organism. In the context of the CBS, the word "toxin" refers only to microbial toxins regulated by the PHAC and the CFIA under the HPTA and the *Health of Animals Act* (HAA). An exhaustive list of toxins regulated under the HPTA is listed in Schedules 1 and 5 of the HPTA; whereas any imported microbial toxin derived from an animal pathogen is also regulated under the HAA. In general, toxins capable of producing human or animal disease are safely handled in CL2 zones, at a minimum. Additional physical containment or operational practice requirements may be necessary, based on risk.

2.3.4 Prions

Prions are small, proteinaceous, infectious particles that are generally considered to be the cause of a number of fatal progressive neurodegenerative diseases in humans and animals known as transmissible spongiform encephalopathies. The most likely route of transmission of infectious prions is through inoculation or ingestion. Prions are resistant to **decontamination** procedures and processes commonly effective against other pathogens. Activities involving infectious prions are generally assessed to be safely conducted at CL2 with specific additional physical and operational requirements. Consequently, for certain requirements presented in Chapters 3, 4, and 5, there are increased or unique requirements for activities with prions indicated by the letter '**P**' in the matrix.

2.3.5 Security Sensitive Biological Agents

Security sensitive biological agents (SSBAs) are human pathogens and toxins that have been determined to pose an increased **biosecurity** risk due to their inherent **dual-use potential** for bioterrorism. In the context of the CBS, SSBAs are the human pathogens and toxins that are identified as "prescribed human pathogens and toxins" in the HPTA and the *Human Pathogens and Toxins Regulations* (HPTR). Prescribed human pathogens are all RG3 and RG4 human pathogens that also appear on the *List of Human and Animal Pathogens and Toxins for Export Control*, published by the Australia Group (as amended from time to time), except for Duvenhage virus, Rabies virus and all other members of the Lyssavirus genus, and Vesicular stomatitis virus. Prescribed toxins are all toxins listed in Schedule 1 of the HPTA that also appear on the *List of Human and Animal Pathogens and Toxins for Export Control*, published by the Australia Group (as amended from time to time), when in a quantity greater than the identified **trigger quantity** in a part of the facility where **controlled activities** with SSBAs are authorized, as described by Section 10(2) of the HPTR. Consequently, for certain requirements presented in Chapters 3, 4, and 5, there are unique requirements for SSBAs at any containment level and, for activities with SSBA toxins in CL2 or CL2-Ag zones, there are increased requirements (as indicated by the letter '**S**' in the CL2 or CL2-Ag column of the matrix). A toxin present in a facility in a quantity below the trigger quantity is not an SSBA; however, it remains a regulated toxin, and subject to

the requirements in the CBS (i.e., the minimum containment level for handling a regulated toxin is CL2). For ease of reference, the PHAC maintains an exhaustive list (as amended from time to time) of all SSBAs, including toxin trigger quantities, on the PHAC website (http://phac-aspc.gc.ca/lab-bio/regul/ssba-abcse-eng.php).

2.3.6 Non-Indigenous Animal Pathogens

Non-indigenous animal pathogens are exotic to Canada (i.e., foreign animal disease agents that are not present in Canada). In the context of the CBS, non-indigenous animal pathogens are pathogens that are listed in the World Organization for Animal Health's *OIE-Listed diseases, infections and infestations* (as amended from time to time) and that are also exotic to Canada. Due to the risk of serious negative health effects to the Canadian animal population and the resultant economic impact, more stringent physical containment and operational practice requirements are applied to containment zones where non-indigenous animal pathogens are imported. Consequently, to prevent their **release** into the environment, there are several unique requirements in Chapters 3, 4, and 5 for activities with non-indigenous animal pathogens, as indicated in the text of the requirement itself. The CFIA continues to oversee the facility certification program for facilities approved to handle or store imported non-indigenous animal pathogens. Emerging animal disease pathogens are administered by the CFIA as non-indigenous animal pathogens due to the high risk of serious negative effects associated with these pathogens. For ease of reference, example lists of non-indigenous animal pathogens and emerging disease pathogens, sorted by risk group, are available through the Automated Import Reference System (AIRS) on the CFIA website (http://www.inspection.gc.ca/airs).

2.3.7 Large Scale Work

The PHAC and the CFIA generally consider activities involving volumes of toxins or the *in vitro* culture of infectious material on a scale of 10 litres or greater to be large scale; this could be a single vessel with a volume of 10 litres or greater or, in some cases, multiple vessels with a total volume of 10 litres or greater. Large scale production facilities, such as industrial fermentation and vaccine production plants, pose an increased risk to personnel and the environment due to the large quantities of infectious material or toxins being handled. As such, there are sometimes more stringent requirements and additional considerations when compared to laboratory work areas at the same containment level. Chapters 3, 4, and 5 describe several additional requirements particular for containment zones where activities with large scale volumes of infectious material or toxins occur, as indicated in the text of the requirement itself. It will be determined in consultation with the PHAC and the CFIA on a case-by-case basis whether or not particular activities conducted in a containment zone are required to follow the increased or unique requirements for large scale work areas.

2.3.8 Handling Risk Group 1 Biological Material

The legislation administered by the PHAC and the CFIA does not apply to RG1 human and animal pathogens. The CBS does not specify the requirements for activities with RG1 material; however, due care should be exercised and safe work practices (e.g., **good microbiological laboratory practices**) should be followed when handling these materials since RG1 biological material does pose a low risk to the health of individuals or animals.

2.4 Working with Animals

Pathogen and toxin work performed *in vivo* involves living animals and is carried out in an animal containment zone. An animal containment zone refers to a series of co-located **animal rooms** or **animal cubicles**, as well as associated corridors and support rooms (e.g., storage and preparation areas) of equal containment level. A zone where the animals are contained in **primary containment caging** (i.e., filtered containment caging to prevent the release of infectious material and toxins) is termed a "**small animal containment zone**" (or SA zone). The room where animals are housed in primary containment caging within an SA zone is referred to as an "animal room". Alternatively, a zone where the room itself provides the **primary containment** is termed a "**large animal containment zone**" (or LA zone). The room or space within the LA zone in which animals are housed is referred to as an "animal cubicle". LA zones may also include animal **post mortem rooms** (PM rooms). In the context of the CBS, the term "post mortem room" is specific to rooms in LA zones where animal necropsies and dissections are conducted.

It is important to note that the designation as an SA zone or LA zone is dependent on the way in which the animal is housed (primary containment caging versus the room providing containment) rather than the actual physical size of the animal. In general, **large-sized** animals and **small-sized** animals are housed in LA zones and SA zones, respectively. However, in some cases, small-sized animals can be housed in an LA zone. For example, a room where small-sized animals are housed in **open caging** only intended for the confinement of animals to an area (i.e., it does not include filtration to prevent the release of infectious material and toxins) is considered to be an animal cubicle inside an LA zone, despite the actual size of the animal. Animal cubicles and PM rooms in LA zones require additional and sometimes unique physical containment and operational practice requirements in order to contain the pathogens and toxins and protect personnel entering these spaces from **exposure**. These requirements are identified under the agriculture (i.e., Ag) column.

2.5 Derogations and Exemptions to Physical or Operational Requirements

As part of the ongoing pathogen risk assessments and containment level assessments conducted by the PHAC and the CFIA, the containment level required for handling a pathogen may change over time and specific physical containment or operational practice requirements may be derogated (i.e., lessened) in conjunction with the implementation of additional risk mitigation strategies to address the specific pathogen. For example, many of the physical containment and operational practice requirements at CL3 are aimed at reducing the risks associated with **airborne** or **aerosol**-transmitted pathogens; work with RG3 pathogens not known to be transmissible by inhalation may allow certain physical or operational requirements at CL3 to be derogated. The PHAC develops **biosafety** directives that provide a comprehensive overview of the customized containment level requirements for activities with specific pathogens, or groups of pathogens, when the containment level differs from the risk group (e.g., RG3 pathogens handled in CL2). Derogations approved by the PHAC and/or the CFIA would be stipulated in the **licence** or **animal pathogen import permit**.

Exemptions to specific physical or operational requirements will be considered by the PHAC and the CFIA, provided that it can be demonstrated by the regulated party that the intent of the requirement in question has been met through an alternative mechanism, as determined by an LRA. All such exemptions will be evaluated on a case-by-case basis.

2.6 Matrix Layout: Chapters 3, 4, and 5

The requirements for facilities where pathogens, toxins, and other regulated infectious material are handled or stored are provided in Chapters 3, 4, and 5. The requirements are risk- and evidence-based, and, where possible, more performance-based than explicitly prescriptive. Chapter 3 describes the physical containment requirements (i.e., engineering controls and facility design) that are to be met prior to the handling or storing of infectious material or toxins. Chapter 4 describes the operational practice requirements (i.e., administrative controls and procedures) to be implemented in order to mitigate risks and protect personnel, the community, and the environment in relation to the handling of infectious material or toxins. Chapter 5 provides the requirements for the performance and **verification** tests necessary to demonstrate compliance with the physical containment requirements outlined in Chapter 3 and, in some cases, the operational practice requirements outlined in Chapter 4.

The requirements in Chapters 3, 4, and 5 are presented in a series of matrices (or tables). Each matrix has been laid out to illustrate which requirements apply to specific containment levels and in some cases, to specific work areas. The requirements are grouped by topic into multiple matrices that contain separate CL2, CL3, and CL4 columns. Rather than grouping

requirements by containment level within a given matrix, they are instead organized to facilitate comparison and contrast of requirements related to a similar topic. This helps to illustrate how the requirements at higher containment levels build on those of lower levels of containment. Different types of work areas inside a containment zone are included in each column of the matrices as summarized in Table 2-1. Since there are numerous additional physical containment and operational practice requirements necessary for animal containment zones where the room itself provides the primary containment, LA zones at CL2 and CL3 are represented by separate columns, and are designated as CL2- and CL3- "Agriculture" (i.e., CL2-Ag and CL3-Ag, respectively). The remaining work areas (laboratory work areas, large scale production areas, and SA zones) are all represented under the CL2 and CL3 columns. The requirements in the CL4 column encompass all work areas.

Table 2-1. Summary of the types of work areas included in each column of the matrices.

Type of work area(s)	CL2*	CL2-Ag*	CL3	CL3-Ag	CL4
Laboratory work areas	✓		✓		✓
Large scale production areas	✓		✓		✓
SA zones† (including animal rooms)	✓		✓		✓
LA zones‡ (including animal cubicles and PM rooms, where applicable)		✓		✓	✓

* includes activities involving prions or animals infected with prions
† animal containment zones where the animals are housed in primary containment caging
‡ animal containment zones where the room itself provides the primary containment

In most cases, the requirements for all work areas within a column of the matrices are the same (e.g., CL2 laboratory work area, large scale production area, and SA zones). In some instances, the requirement itself will reference a particular type of work area (e.g., "large scale", "animal work", "SA zone", "animal rooms", "animal cubicles", "PM rooms") to which it applies and a closed box will appear in the columns (■). In the case that a requirement applies to CL2 SA zones and CL2 large scale zones, but is not required for CL2 laboratory work areas, an open box (□) appears in the CL2 column.

In instances where the requirements differ for different work areas, the exceptions are listed in square brackets below the requirement (e.g., "[Not required for CL2 SA zones.]"). The absence of a symbol in a column indicates that the element is not required for that containment level. The description of the symbols and an example of the matrix layout is provided in Figure 2-1.

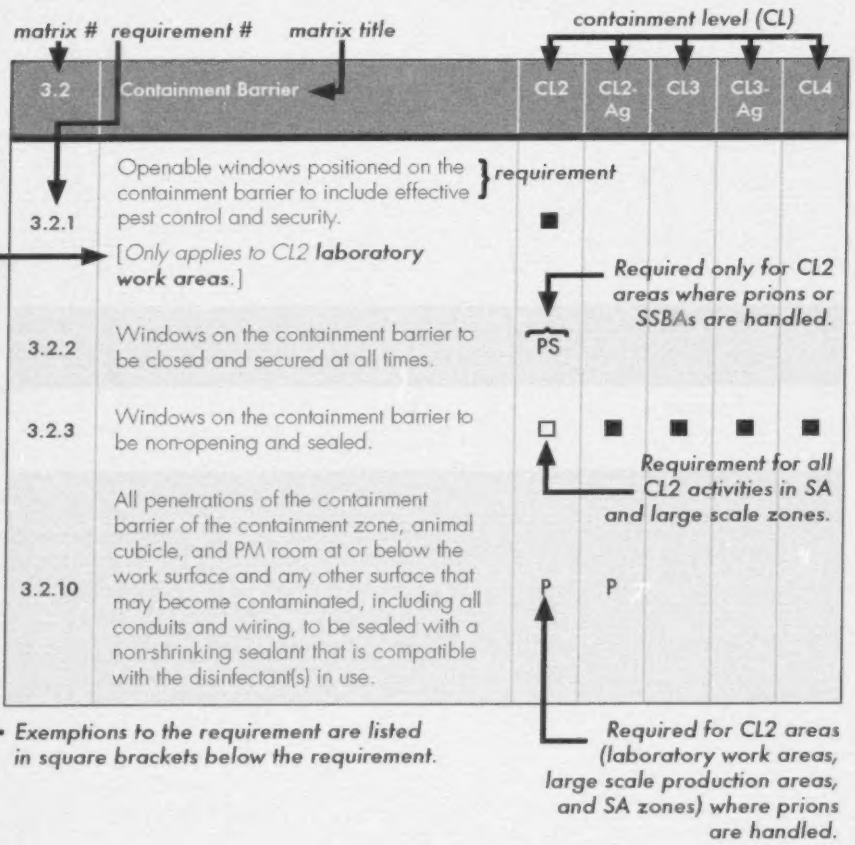
Throughout Chapters 3, 4, and 5, the following symbols and combinations are used:

■	**Required for all containment zones, including work areas where activities with prions and SSBAs are conducted**

For CL2 and CL2-Ag zones, the following symbols are used to facilitate the identification of the applicable requirements.

□	**Required for all CL2 SA zones and CL2 large scale production areas including CL2 SA zones and CL2 large scale production areas where activities with prions or SSBAs are conducted; not required, for CL2 laboratory work areas**
P	**Required for all work areas where activities with prions are conducted**
S	**Required for all work areas where activities with SSBAs are conducted**
PS	**Required for all work areas where activities with prions or SSBAs are conducted**
□ P	**Required for all CL2 SA zones and CL2 large scale production areas, as well as for CL2 laboratory work areas where activities with prions are conducted**
□ PS	**Required for all CL2 SA zones and CL2 large scale production areas, as well as for CL2 laboratory work areas where activities with prions or SSBAs are conducted**

Figure 2-1: Example of the matrix layout and the symbols found in Chapters 3, 4, and 5.


matrix #
requirement #
matrix title
containment level (CL)
3.2
Containment Barrier
CL2
CL2-Ag
CL3
CL3-Ag
CL4
3.2.1
Openable windows positioned on the containment barrier to include effective pest control and security.
requirement
[Only applies to CL2 laboratory work areas.]
3.2.2
Windows on the containment barrier to be closed and secured at all times.
PS
Required only for CL2 areas where prions or SSBAs are handled.
3.2.3
Windows on the containment barrier to be non-opening and sealed.
Requirement for all CL2 activities in SA and large scale zones.
3.2.10
All penetrations of the containment barrier of the containment zone, animal cubicle, and PM room at or below the work surface and any other surface that may become contaminated, including all conduits and wiring, to be sealed with a non-shrinking sealant that is compatible with the disinfectant(s) in use.
P
P
Exemptions to the requirement are listed in square brackets below the requirement.
Required for CL2 areas (laboratory work areas, large scale production areas, and SA zones) where prions are handled.

2.7 Explanatory Notes

The Explanatory Notes, found in the Appendix, provide additional information to identify the risk(s) that are being mitigated by each requirement listed in Chapters 3, 4, and 5. The Explanatory Notes also provide examples of how the requirement can be achieved. The Explanatory Notes for the requirements listed in Chapter 5 provide more details on the tests to be performed. The Explanatory Notes are organized in such a way that each requirement in Chapters 3, 4, and 5 has a corresponding entry in the Explanatory Notes, following the same numbering convention. It is important to note that the examples included in the Explanatory Notes are not provided as specific requirements or recommendations; rather they are provided for clarification and represent typical means of meeting a requirement.

2.8 The *Canadian Biosafety Handbook*

The *Canadian Biosafety Handbook* (CBH), 2nd Edition, 2015, is a companion document to the CBS that provides the core information and guidance on how the biosafety requirements outlined in the CBS can be achieved. The second edition of the CBH provides an update of the Guidelines provided in Part II of the *Canadian Biosafety Standards and Guidelines* (CBSG), 1st Edition, 2013. The CBH is structured to systematically address the concepts required for the development of a comprehensive risk-based biosafety management program. The CBH provides general guidance for containment zone personnel rather than specific guidance or **standard operating procedures** (SOPs) for individual pathogens.

CHAPTER 3

PHYSICAL CONTAINMENT REQUIREMENTS

CHAPTER 3 – PHYSICAL CONTAINMENT REQUIREMENTS

This chapter describes the **physical containment requirements** designed to mitigate the **risks** associated with **handling or storing pathogens**, **toxins**, infected animals, or other regulated **infectious material**. Physical containment is achieved through specific physical barriers provided by engineering controls and **facility** design. The phrase "in accordance with function" is included in some requirements where the specific activities and procedures performed in the **containment zone** (i.e., the function) may influence how the requirement is implemented. Details on the use and interpretation of the matrices that follow are provided in Chapter 2. A description of the symbols used appears in Section 2.6.

3.1 Structure and Location

The site selection process for a **containment zone** generally includes an assessment of local programs and the local environment. Consideration of the **risks**, including the impact of possible **pathogen** or **toxin release**, is important at the beginning of the design phase and before construction work begins. In areas prone to natural disasters, buildings and support systems for containment zones may need to meet more stringent building codes.

3.1	Structure and Location	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.1.1	Containment zones to be separated from public and **administrative areas** by a door.	■	■	■	■	■
3.1.2	Dedicated paper/computer work stations within the containment zone to be segregated from **laboratory** work stations, **animal rooms, animal cubicles**, and **post mortem rooms** (PM rooms).	■	■	■	■	■
3.1.3	Structure and location of containment zone to be designed to withstand internal and external environmental factors.				■	■
3.1.4	**Laboratory work areas** to be located outside of animal cubicles.		■		■	■
3.1.5	Cold storage area or equipment to be provided in, or adjacent to, the PM room.		■		■	■

3.2 Containment Barrier

The **containment barrier** refers to the physical structure(s) or obstruction(s) present that create a boundary between the "clean" and "dirty" areas of a **containment zone**. The containment barrier itself is created by the walls, doors, floors, and ceilings of a room that physically enclose the areas where **infectious material**, **toxins**, and/or infected animals are handled or stored. In containment zones where **inward directional airflow** (IDA) is provided, the containment barrier is also maintained through negative air pressure differentials and IDA. Points of access through the containment barrier are provided through doors and **anterooms**. Equipment such as **dunk tanks**, **pass-through chambers**, and double-door barrier autoclaves, are examples of penetrations of the containment barrier.

3.2	Containment Barrier	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.2.1	Openable windows positioned on the containment barrier to include effective pest control and security. [*Only applies to CL2* ***laboratory work areas***.]	■				
3.2.2	Windows on the containment barrier to be closed and secured at all times.	PS				
3.2.3	Windows on the containment barrier to be non-opening and sealed.	□	■	■	■	■
3.2.4	Window glazing material to provide the appropriate level of security as determined by a **biosecurity risk assessment**.	□ PS	■	■	■	■
3.2.5	Windows on the containment barrier to be positioned to prevent public viewing into **animal rooms**, **animal cubicles**, and **post mortem rooms** (PM rooms). [*Not required for CL2* ***large scale*** *production areas.*]	□	■	■	■	■
3.2.6	Equipment located on the containment barrier to be designed and installed in a manner that maintains the integrity of the containment barrier.			■	■	■

3.2	Containment Barrier	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.2.7	**Pass-through technologies** on the containment barrier to be equipped with doors that have mechanical or electronic **interlocks** (preferred), or visual/audible alarms, or other acceptable mechanism, that prevent the simultaneous opening of both doors.			■		
3.2.8	Pass-through technologies on the containment barrier to be equipped with doors that have mechanical or electronic interlocks that prevent the simultaneous opening of both doors.				■	
3.2.9	Doors of pass-through technologies on the containment barrier to be equipped with mechanical or electronic interlocks and visual/audible alarms that prevent the simultaneous opening of both doors.					■
3.2.10	All penetrations of the containment barrier of the containment zone, animal cubicle, and PM room at or below the work surface and any other surface that may become contaminated, including all conduits and wiring, to be sealed with a non-shrinking sealant that is compatible with the disinfectant(s) in use.	P	P			
3.2.11	All penetrations of the containment barrier, including all conduits and wiring, to be sealed with a non-shrinking sealant that is compatible with the disinfectant(s) in use.			■	■	■
3.2.12	All penetrations of the containment barrier inside animal cubicles and PM rooms, including all conduits and wiring, to be sealed with a non-shrinking sealant that is compatible with the disinfectant(s) in use.				■	■

3.3 Access

Physical and **security barriers** (e.g., doors, locks, **anterooms, interlocks**) at points of entry into and exit from the **containment zone** are critical to maintaining containment integrity and allowing only trained and authorized individuals access to the zone. In **high containment zones**, the physical barriers help maintain **inward directional airflow** (IDA) and provide space so that contaminated or potentially contaminated **personal protective equipment** (PPE) remains inside the **containment barrier**.

3.3	Access	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.3.1	Doors to the containment zone to be lockable.	■	■	■	■	■
3.3.2	Biohazard warning signage (including the international biohazard warning symbol, **containment level**, name and telephone number[s] of contact person, and entry requirements) to be posted at the containment zone point(s) of entry.	■	■	■	■	■
3.3.3	Where unique hazards exist, project-specific signage to be posted at the **animal room**, **animal cubicle**, and **post mortem room** (PM room) point(s) of entry.	■	■	■	■	■
3.3.4	**Restricted access** into the part of the **facility** where **security sensitive biological agents** (SSBAs) are stored and handled to be provided through a **controlled access system**.	S	S	■	■	
3.3.5	Restricted access into the containment zone to be provided through a controlled access system.	□ P	■	■	■	■
3.3.6	Restricted access into each animal room, animal cubicle, and PM room to be provided through a controlled access system or other acceptable mechanism.			■	■	■

3.3	Access	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.3.7	Non-reproducible keys to be used when key-locks are used as the controlled access system.	□ PS	■	■	■	■
3.3.8	Electronic controlled access system to the containment zone, where provided, to be backed up with an alternate controlled access system or other acceptable means.			■	■	■
3.3.9	Space to be provided for the storage of PPE in use.	■	■	■	■	■
3.3.10	Dedicated change area to be provided at personnel entry to the containment zone to allow for separation of personal clothing from dedicated containment zone clothing (i.e., **"clean" change area** separated from **"dirty" change area**).	□ P	■	■	■	■
3.3.11	Anteroom(s) to be provided at the point(s) of entry into/exit from the containment zone.	□		■		■
3.3.12	Anteroom(s) to be provided at the point(s) of entry into/exit from: • the containment zone; <u>or</u> • each animal cubicle and PM room.		■			
3.3.13	Anteroom(s) to be provided for entry into/exit from: • the containment zone; <u>and</u> • each animal cubicle and PM room (except entry/exit through the dirty corridor).				■	/

3.3	Access	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.3.14	Anteroom(s) at the point(s) of exit from the containment zone to include: • a walk-through body shower, located on the containment barrier between the "dirty" and "clean" change areas.			■		
3.3.15	Anteroom(s) at the point(s) of exit from the containment zone and each animal cubicle and PM room (except exit to the dirty corridor) to include: • a walk-through body shower, located on the containment barrier between the "dirty" and "clean" change areas.				■	
3.3.16	Anteroom(s) at the point(s) of exit from the containment zone to include: • a chemical **decontamination** shower and a suit change area (may also be "dirty" change area), in containment zones where positive-pressure suits are worn; and • a walk-through body shower, located on the containment barrier between the "dirty" and "clean" change areas.					■
3.3.17	Anteroom **critical door**(s) to be provided with a physical or operational mechanism that prevents the simultaneous opening with: • the door leading into the anteroom from outside of the containment zone; and • the door(s) leading from the anteroom into the **laboratory work area**/ animal room/animal cubicle/ PM room.		■	■		

3.3	Access	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.3.18	Anteroom critical door(s) to be provided with mechanical or electronic interlocks (equipped with manual overrides for emergency exit) that prevent the simultaneous opening with: • the door leading into the anteroom from outside of the containment zone; and • the door(s) leading from the anteroom into the laboratory work area/animal room/animal cubicle/PM room.				■	■
3.3.19	Chemical decontamination shower doors to be provided with mechanical or electronic interlocks (equipped with manual overrides for emergency exit) that prevent the simultaneous opening of doors. *[Not required in laboratory work areas where **infectious material** is exclusively handled in a Class III **biological safety cabinet** (BSC) line.]*					■
3.3.20	**Sealable doors** to be provided at the point(s) of animal entry into animal cubicles (i.e., between the cubicle and corridor) and PM rooms (i.e., between PM room and corridor), except doors to the dirty corridor.				■	■

3.3	Access	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.3.21	**Airtight doors** to be provided for entry, including: • the chemical decontamination shower doors; • the inner and outer doors of the anteroom(s) dedicated to the entry of animals and equipment into the containment zone; and • any critical door directly on the containment barrier. [*Not required for CL3-Ag zones where only human and/or indigenous* ***animal pathogens*** *are handled or CL4 laboratory work areas where infectious material is exclusively handled in a Class III BSC line.*]				■	■

3.4 Surface Finishes and Casework

Selecting the appropriate surface finishes and casework for containment zones is necessary to facilitate the maintenance, cleaning, and decontamination of surfaces within the zone. Surface finishes also help protect against the stresses associated with activities routinely performed within the containment zone, such as repeated decontamination and frequent high pressure washing in animal containment zones.

3.4	Surface Finishes and Casework	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.4.1	Surfaces and interior coatings, including, but not limited to, floors, ceilings, walls, doors, frames, casework, benchtops, and furniture, to be cleanable, non-absorbent, and resistant to scratches, stains, moisture, chemicals, heat, impact, repeated decontamination, and high pressure washing, in accordance with function.	■	■	■	■	■
3.4.2	Surfaces to be continuous with adjacent and overlapping materials.	□ P	■	■	■	■
3.4.3	Benches, doors, drawers, handles, and shelving to have smooth rims and corners where positive-pressure suits are worn.					■
3.4.4	Backsplashes, when installed tight to the wall, to be sealed at the wall-bench junction and continuous with work surfaces.	□ P	■	■	■	■
3.4.5	Floors to be slip-resistant in accordance with function.	■	■	■	■	■
3.4.6	Floors in **animal rooms, animal cubicles, post mortem rooms** (PM rooms), and corridors to withstand loading, in accordance with function. [*Not required for CL2* ***large scale*** *production areas.*]	□	■	■	■	■

3.4	Surface Finishes and Casework	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.4.7	Continuity of seal to be maintained between the floor and wall.	□ P	■	■	■	■
3.4.8	Continuity of seal to be maintained between the wall and ceiling.		■	■	■	■
3.4.9	Interior surface materials to restrict penetration of gases and liquids used for decontamination and/or **laboratory** purposes.		■	■	■	■
3.4.10	Protruding obstructions to be minimized and appropriately shielded in animal cubicles and corridors.		■		■	■

3.5 Air Handling

The heating, ventilation, and air conditioning (HVAC) systems can be designed to create a defined **containment barrier** to minimize the spread of infectious **aerosols** or aerosolized **toxins**. These systems, particularly in **high containment zones**, incorporate secondary containment barriers such as **inward directional airflow** (IDA) and **high efficiency particulate air (HEPA) filters** for exhaust air.

3.5	Air Handling	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.5.1	IDA to be provided where: • **pathogens** that are primarily infectious through inhalation are handled; or • infectious aerosols or aerosolized toxins may be generated by procedures in use. [*Not required for SA zones.*]	□	■			
3.5.2	IDA to be provided and maintained under normal operation of the HVAC system.			■	■	■
3.5.3	Monitoring device(s) that visually demonstrate IDA to be provided for the containment zone.		■	■	■	■
3.5.4	Pressure differential monitoring lines penetrating the containment barrier to be provided with HEPA filtration or acceptable alternative. [*Not required for CL3 zones with airtight pressure differential monitoring devices.*]			■	■	■
3.5.5	Audible or visual alarms that signal HVAC systems failure to be provided to alert containment zone personnel inside and outside the containment zone.			■	■	■

3.5	Air Handling	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.5.6	Supply and exhaust air systems to be independent of other areas. CL3 air systems may be combined with areas of lower containment when provided with effective **backdraft protection**.			■	■	■
3.5.7	Supply air duct to areas inside the containment barrier to be provided with effective backdraft protection capable of isolation from inside or outside of the containment barrier.			■	■	
3.5.8	Supply air to be HEPA filtered.					■
3.5.9	Supply and exhaust air systems to be provided with automatic mechanical/electronic **interlocks** that prevent sustained positive pressurization of the containment zone.			■	■	■
3.5.10	Where IDA is provided, exhaust air to be: • passed through a filter that prevents the **release** of **infectious material** or toxins; or • 100% exhausted directly to the outdoors. [*Not required for SA zones.*]	□	■			
3.5.11	Exhaust air to be passed through HEPA filtration.			■	■	

3.5	Air Handling	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.5.12	Exhaust air to be passed through two stages of HEPA filtration.					■
3.5.13	HEPA filters to conform to IEST-RP-CC001.5.			■	■	■
3.5.14	HEPA filter housings to be designed to withstand structural changes at applied pressure of 1000 Pa (i.e., 4 inches water gauge [in. w.g.]) in accordance with ASME N511 and AG-1.			■	■	■
3.5.15	HEPA filter housings to be designed to allow ***in situ*** filter isolation, **decontamination**, and testing.			■	■	■
3.5.16	Supply air ductwork located between the containment barrier and backdraft protection to be sealed airtight in accordance with ANSI/SMACNA 016 Seal Class A.			■	■	■
3.5.17	Exhaust air ductwork located between the containment barrier and HEPA filter(s) or **isolation damper**(s) to be sealed airtight in accordance with ANSI/SMACNA 016 Seal Class A.			■	■	■
3.5.18	Effective airflow control devices to be provided on supply and exhaust air systems.			■	■	■
3.5.19	Sections of supply and exhaust air systems located outside the containment barrier to be accessible for maintenance and repair.					■

3.6 Facility Services

Facility services include all plumbing, electrical, and other services related to the operation of the **containment zone**.

3.6	Facility Services	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.6.1	Exposed conduits, piping, and other services to be mounted to allow for **decontamination** of all surfaces.	□	■	■	■	■
3.6.2	Individual and/or dedicated main water supply shut-off valves and other controls to be located and accessible from outside the containment zone.			■	■	■
3.6.3	Water supply services to be provided with isolation valve and **backflow prevention** in accordance with CAN/CSA-B64.10/B64.10.1.		P	■	■	■
3.6.4	Sinks to be provided and located to facilitate handwashing upon exit from the containment zone. *[Not required for CL4 zones where positive-pressure suits are worn.]*	■	■	■	■	■
3.6.5	Sinks provided for handwashing to be equipped with "hands-free" capability. *[Not required for CL4 zones where positive-pressure suits are worn.]*	□	■	■	■	■
3.6.6	Emergency eyewash and shower equipment to be provided in accordance with containment zone activities. *[Not required for CL4 zones where positive-pressure suits are worn.]*	■	■	■	■	■

3.6	Facility Services	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.6.7	Containment zone to be designed to control the **release** of **large scale** process fluids into sanitary sewers. [*Not required for CL2 SA zones.*]	□		■		■
3.6.8	Containment zone to be designed to contain the release of the full volume of large scale process fluids.			■		■
3.6.9	Drains to be equipped with **deep seal traps** of sufficient depth to maintain water seal and to prevent suction of liquid **wastes** back into containment zone.			■	■	■
3.6.10	Containment zone drain piping servicing areas inside the **containment barrier** to be independent from those of other areas and directly connected to an **effluent decontamination system**. [*In CL3 zones, only required where **non-indigenous animal pathogens** are handled.*]		P	■	■	■
3.6.11	Autoclave condensate drains located outside the containment barrier to have a closed connection and be directly connected to the drain piping servicing areas inside the containment barrier, unless condensate is effectively decontaminated prior to release.			■	■	■
3.6.12	Plumbing vent lines to be independent from those of lower containment, unless provided with **high efficiency particulate air (HEPA) filtration** upstream from the connection.			■		

3.6	Facility Services	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.6.13	Plumbing vent lines to be provided with HEPA filtration with a means of isolation and decontamination. [*In CL3 zones, only required where non-indigenous animal pathogens are handled.*]			■	■	
3.6.14	Plumbing vent lines to be independent from those of lower containment and provided with two stages of HEPA filtration with a means of isolation and decontamination.					■
3.6.15	Supplied breathing air and air hose connections to be provided in areas where positive-pressure suits are worn.					■
3.6.16	Backup air supply system that allows sufficient time for emergency evacuation to be provided in areas where positive-pressure suits are worn.					■
3.6.17	Light ballasts and starters to be located outside the containment barrier.					■
3.6.18	Services and equipment critical to maintaining containment and **biosecurity** to be supported by emergency power.	□ PS	■	■	■	■
3.6.19	Life safety systems, building automation systems, and security systems to be supported by uninterrupted power supply (UPS).					■

3.7 Essential Biosafety Equipment

Essential **biosafety** equipment is key to ensuring effective containment of **pathogens, toxins**, and other regulated **infectious material**. This includes all **primary containment devices** (e.g., **biological safety cabinets** [BSCs], isolators, centrifuges with sealable cups, **process equipment**, fermenters, microisolator cages, ventilated cage racks, sealed biological **waste** containers).

3.7	Essential Biosafety Equipment	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.7.1	Certified BSCs and other primary containment devices to be provided, based on work activities.	■	■		■	
3.7.2	Certified BSCs and other primary containment devices to be provided.			■		■
3.7.3	Class II B2 BSCs, where present, to be installed and set-up in a manner to eliminate reversal of airflow from the face of the BSC (i.e., **puff-back**) during a failure of the heating, ventilation, and air conditioning (HVAC) system or the BSC exhaust fan; where elimination of puff-back cannot be achieved, the risk associated with puff-back to be mitigated through physical and operational means.	■	■	■	■	■
3.7.4	Process equipment, **closed systems**, and other primary containment devices to be designed to prevent the **release** of infectious material or toxins.	■	■	■	■	■
3.7.5	Process equipment for **large scale** activities with infectious material or toxins to be equipped with sensing devices to monitor containment integrity during operations and to signal failure. [*Not required for CL2 SA zones.*]	□		■		■

3.7	Essential Biosafety Equipment	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.7.6	BSCs, where present, to be located as far as possible from high traffic areas, doors, openable windows, and air supply/exhaust diffusers.	■	■	■	■	■
3.7.7	Large reusable equipment for large scale activities with infectious material or toxins to be designed and constructed to be effectively cleaned and decontaminated, or sterilized, in a manner that reduces personnel **exposure**. [*Not required for CL2 SA zones.*]	□		■		■
3.7.8	**Primary containment caging** to be provided to house infected animals. [*Not required for large scale production areas.*]	□				
3.7.9	**High efficiency particulate air (HEPA)-filtered** primary containment caging systems, or partial containment caging systems that are housed in HEPA-filtered ventilated enclosures, to be provided to house infected animals. [*Not required for* ***laboratory work areas*** *or large scale production areas.*]			■		

3.7	Essential Biosafety Equipment	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.7.10	Animal cages and **animal cubicles** to be designed to prevent animal escape. [*Not required for CL2 large scale production areas.*]	□	■	■	■	■
3.7.11	**Decontamination technologies** for the **decontamination** of materials to be provided within the **containment zone**, or **standard operating procedures** (SOPs) to be in place to safely and securely move or transport waste out of the containment zone to a designated decontamination area.	■	■			
3.7.12	Decontamination technologies for the decontamination of contaminated materials to be provided inside the **containment barrier**.			■		
3.7.13	Decontamination technologies to be provided on the containment barrier.				■	■
3.7.14	Decontamination technologies to be provided with monitoring and recording devices that capture operational parameters.	■	■	■	■	■
3.7.15	An autoclave, where present, to be capable of operating at the appropriate temperature for decontamination, as determined by **validation**.	■	■	■	■	■

3.7	Essential Biosafety Equipment	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.7.16	Supply tanks for chemical decontamination technologies to be equipped with alarms that signal low levels.			■	■	■
3.7.17	Vacuum systems to be equipped with a mechanism that prevents internal **contamination**.	■	■	■	■	■
3.7.18	Two-way communication system(s) to be provided inside the containment barrier that allows communication between inside the containment barrier to outside the containment zone, in accordance with function.	■	■	■	■	■
3.7.19	Observation windows and/or video equipment to be installed in a manner that allows activities to be visually monitored from outside the containment barrier.					■

3.8 Effluent Decontamination Systems

Effluent decontamination systems prevent the **release** of contaminated liquids into sanitary sewers, and ultimately, the environment. An effluent decontamination system is critical for decontaminating all liquid **waste** generated in CL3 zones where **non-indigenous animal pathogens** are handled, **large animal containment zones** (LA zones) where **prions** are handled, and all CL3-Ag and CL4 zones.

3.8	Effluent Decontamination Systems	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.8.1	An effluent decontamination system appropriate to the work being conducted to be provided. [*In CL3 zones, only required where non-indigenous animal pathogens are handled.*]		P	■	■	■
3.8.2	Effluent decontamination system to be capable of operating at the appropriate parameters for **decontamination**, as determined by **validation**.		P	■	■	■
3.8.3	Drain piping connected to an effluent decontamination system to be sloped to ensure gravity flow.		P	■	■	■
3.8.4	Effluent decontamination system to be heat and chemical resistant consistent with use.		P	■	■	■

3.8	Effluent Decontamination Systems	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.8.5	Rooms housing an effluent decontamination system serving as a **primary decontamination technology** to: • have lockable doors; • have doors with biohazard warning signage; • have sealed floor surfaces; • have floor drains that are sealed or re-routed to the effluent decontamination system; and • have suitable **personal protective equipment** (PPE) and a spill kit available for emergency response.		P		■	
3.8.6	Rooms housing an effluent decontamination system serving as a primary decontamination technology to: • have lockable doors; • have doors with biohazard warning signage; • contain the release of the full volume of the largest holding tank operating capacity of the effluent decontamination system; • have sealed floor surfaces; • have floor drains that are sealed or re-routed to the effluent decontamination system; • maintain **inward directional airflow** (IDA); • have an **anteroom** for entry/exit; • have **high efficiency particulate air (HEPA) filtration** on exhaust air; and • have suitable PPE and a spill kit available for emergency response.					■

3.8	Effluent Decontamination Systems	CL2	CL2-Ag	CL3	CL3-Ag	CL4
3.8.7	Effluent decontamination system to include a mechanism that prevents blockages.		P	■	■	■
3.8.8	Alarm system to be provided to indicate warnings and failure of effluent decontamination system.		P	■	■	■
3.8.9	Thermally controlled effluent decontamination systems to be equipped with temperature monitoring devices that are calibrated annually.		P	■	■	■
3.8.10	Drain piping connected to an effluent decontamination system to be identified with labels.		P	■	■	■
3.8.11	Drain piping leading to an effluent decontamination system to be accessible for maintenance and repair.		P	■	■	■
3.8.12	Effluent decontamination system vent lines to be provided with HEPA filtration.			■	■	
3.8.13	Effluent decontamination system vent lines to be provided with two stages of HEPA filtration.					■

CHAPTER 4

OPERATIONAL PRACTICE REQUIREMENTS

CHAPTER 4 – OPERATIONAL PRACTICE REQUIREMENTS

This chapter describes the **operational practice requirements** designed to mitigate **risks** associated with handling **or storing pathogens, toxins**, or other regulated **infectious material**, including infected animals. Operational practice requirements are achieved through specific administrative controls and by performing specific documented procedures. Although the requirements in this chapter are specified for each **containment zone**, institutions or organizations may decide to combine certain **biosafety** program elements (e.g., **Biosafety Manual**, **biological safety officer** (BSO), **biosecurity** plan) for multiple containment zones, as determined by an **overarching risk assessment**. The majority of requirements in this chapter are to be based on a **local risk assessment** (LRA) whether it is indicated in the text or not. Details on the use and interpretation of the matrices that follow are provided in Chapter 2. A description of the symbols used appears in Section 2.6.

4.1 Biosafety Program Management

A **biosafety** program is designed to prevent infections, **intoxications**, and illnesses among personnel and to protect the **community** and the environment from harm by preventing the **release** of **pathogens** or **toxins**. The level of detail and complexity of the biosafety program will depend on the nature of the organization (i.e., size, structure, and complexity) and the activities performed within it. A key to the success of any biosafety program is a strong commitment and involvement by everyone within the organization, including senior management, supervisors, and individual personnel. The day-to-day management of the biosafety program can be determined internally and responsibilities delegated accordingly.

4.1	Biosafety Program Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
Administrative Controls						
4.1.1	A biosafety program to be in place for the oversight of safety and containment practices.	■	■	■	■	■

4.1	Biosafety Program Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.1.2	A biosafety representative(s) (i.e., designated **biological safety officer** [BSO] in licensed **facilities**) with the knowledge appropriate for the **containment levels** and pathogens and toxins handled, to be designated for the oversight of biosafety and **biosecurity** practices including: • verifying the accuracy and completeness of **licence** applications, **animal pathogen import permit** applications, and **transfer** applications for the **movement** of material imported under the *Health of Animals Act* (HAA) and *Health of Animals Regulations* (HAR), as applicable; • communicating with the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) on behalf of the licence holder and animal pathogen import permit holder, as applicable; • promoting and monitoring compliance with applicable legislation (including the *Human Pathogens and Toxins Act* [HPTA], *Human Pathogens and Toxins Regulations* [HPTR], HAA, and HAR), conditions of licence and applicable conditions of animal pathogen import permits; applicable biosafety and biosecurity standards, and the **Biosafety Manual** and **standard operating procedures** (SOPs), which includes, but is not limited to; o arranging and documenting appropriate biosafety and biosecurity training for personnel pertaining to human and **animal pathogens** and toxins, as applicable; 4.1.2 continued on page 52 ...	■	■	■	■	■

4.1	Biosafety Program Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.1.2	... 4.1.2 continued from page 51 ○ informing the PHAC of all occurrences of inadvertent possession of a human pathogen or toxin not already authorized by the licence; ○ informing the PHAC of every situation where a shipment of a **security sensitive biological agent** (SSBA) has not been received within 24 hours of when it was expected; ○ conducting periodic inspections and biosafety audits and reporting the findings to the licence holder and the animal pathogen import permit holder, as applicable; ○ informing the licence holder and animal pathogen import permit holder, as applicable, in writing of any non-compliance by a person working with human or animal pathogens, toxins, or other regulated **infectious material** that is not being corrected by that person after they have been made aware of it; • assisting in the development and maintenance of the Biosafety Manual and SOPs; • assisting with internal investigations of **incidents**.	■	■	■	■	■
4.1.3	Contact information provided to the PHAC and the CFIA, as applicable, to be kept up to date.	■	■	■	■	■

4.1	Biosafety Program Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.1.4	**Program intent** to be documented and kept up to date.	■	■	■	■	■
4.1.5	Where **non-indigenous animal pathogens** are handled, changes in program intent and changes in SOPs that impact **biocontainment** or biosafety to be submitted to the CFIA for review prior to implementation.			■	■	■
Risk Assessments and Planning						
4.1.6	An **overarching risk assessment** to be conducted and documented to identify the hazards and appropriate mitigation strategies for the proposed activities involving infectious material or toxins.	■	■	■	■	■
4.1.7	A **biosecurity risk assessment** to be conducted and documented.	■	■	■	■	■
4.1.8	A **local risk assessment** (LRA) to be conducted to examine each task involving infectious material or toxins so that the **risks** are identified and safe work practices developed and documented.	■	■	■	■	■
4.1.9	A **training needs assessment** to be conducted.	■	■	■	■	■

4.1	Biosafety Program Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
Biosafety Program Elements						
4.1.10	A Biosafety Manual to be developed, implemented, kept up to date, made available to personnel inside and outside of **containment zone**, and to contain institutional biosafety policies, programs, and plans, based on an overarching risk assessment and LRAs. The Biosafety Manual to include: • the program intent; • a brief description of the physical design and operation of the containment zone and systems; • a description of the: o biosafety program; o biosecurity plan; o **medical surveillance program**; o training program; o **emergency response plan** (ERP) and incident reporting procedures; o housekeeping program; o facility and equipment maintenance program for components of the containment zone, including integrity testing of **primary containment devices**; and • SOPs for safe work practices specific to the containment zone.	■	■	■	■	■

4.1	Biosafety Program Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.1.11	A biosecurity plan, based on a biosecurity risk assessment, to be developed, implemented, evaluated and improved as necessary, and kept up to date. The biosecurity plan to include mitigation strategies for the risks associated with: • physical security; • personnel suitability and reliability; • accountability for pathogens, toxins, and other regulated infectious material; • **inventory**; • incident and emergency response; and • information management.	■	■	■	■	■
4.1.12	A medical surveillance program, based on an overarching risk assessment and LRAs, to be developed, implemented, and kept up to date.	■	■	■	■	■
4.1.13	A respiratory protection program to be in place when respirators are in use.	■	■	■	■	■
4.1.14	A training program, based on a training needs assessment, to be implemented, evaluated and improved as necessary, and kept up to date.	■	■	■	■	■

4.1	Biosafety Program Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.1.15	SOPs specific to the nature of the work being conducted in the containment zone to be developed and documented, including: • **personal protective equipment** (PPE) requirements; • entry/exit procedures for personnel, animals, and materials; • use of primary containment devices; • animal work considerations; • **decontamination** and **waste** management; • the safe and secure movement and **transportation** of infectious material and toxins, and • any procedure or task involving infectious material, toxins, and/or infected animals, as determined by an LRA.	■	■	■	■	■
4.1.16	An ERP, based on an overarching risk assessment and LRAs, to be developed, implemented, and kept up to date.	■	■	■	■	■

4.2 Medical Surveillance Program

The **medical surveillance program** aims to prevent and detect illnesses related to **exposure** of personnel to **pathogens** or **toxins** and to provide a response mechanism through which potential infections and **intoxications** can be quickly identified and treated before serious injury, **disease**, or transmission to the public occurs.

4.2	Medical Surveillance Program	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.2.1	Liaison to be established with the local hospital/health care **facility**.					■
4.2.2	**Containment zone** personnel to immediately inform appropriate internal personnel or authority of any: • **incident** that may have resulted in an exposure of an individual to a human pathogen or toxin in a facility; or • disease that may have been caused by an exposure to a human pathogen or toxin in a facility.	■	■	■	■	■
4.2.3	Supervisors to contact any containment zone personnel with unexpected work absences.					■
4.2.4	Emergency medical contact card to be issued to containment zone personnel handling non-human primates or a pathogen identified by a **local risk assessment** (LRA).	■	■	■	■	
4.2.5	Emergency medical contact card to be issued to containment zone personnel.					■

4.3 Training Program

Training is a core element of **biosafety** and **biosecurity**, and is essential to the success of the biosafety program. It is critical that personnel be knowledgeable about the hazards associated with the **pathogens** and **toxins** present in the work environment and the practices and tools that can protect them from these hazards. The training program encompasses both education (i.e., theoretical) and training (i.e., practical).

4.3	Training Program	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.3.1	Personnel to be trained on the relevant components of the **Biosafety Manual** and **standard operating procedures** (SOPs), as determined by the **training needs assessment**.	■	■	■	■	■
4.3.2	Personnel to be trained on the potential hazards associated with the work involved, including the signs and symptoms of **disease**(s) caused by the **infectious material** or toxins in use and the necessary precautions to prevent **exposure** to, or **release** of, pathogens or toxins.	■	■	■	■	■
4.3.3	Personnel to be trained on the relevant physical design and operation of the **containment zone** and **containment systems**.	■	■	■	■	■
4.3.4	Personnel to be trained on the correct use and operation of **laboratory** equipment, including **primary containment devices**.	■	■	■	■	■
4.3.5	Personnel working with animals to be trained in restraint and handling techniques.	■	■	■	■	■

4.3	Training Program	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.3.6	Visitors, maintenance and janitorial staff, contractors, and others who require temporary access to the containment zone to be trained and/or accompanied in accordance with their anticipated activities in the containment zone.	■	■	■	■	■
4.3.7	Personnel to demonstrate knowledge of and proficiency in the SOPs on which they were trained.	■	■	■	■	■
4.3.8	Trainees to be supervised by **authorized personnel** when engaging in activities with infectious material and toxins until they have fulfilled the training requirements.	■	■	■	■	■
4.3.9	Review of training needs assessment to be conducted, at minimum, annually. Additional or refresher training to be provided as determined by the review process or when warranted by a change in the biosafety program.	■	■	■	■	■
4.3.10	Refresher training on emergency response procedures to be provided annually.	■	■	■	■	■

4.4 Personal Protective Equipment

Personal protective equipment (PPE) includes protective equipment and clothing that are designed to minimize the **risk** of **exposure** to **pathogens** and **toxins**. PPE serves as a last line of defence to prevent exposure in the event of failure in the administrative or engineering controls. The exception to this is in **animal cubicles** and **post mortem rooms** (PM rooms), where PPE is the primary defence for personnel against exposure. Selection of PPE is determined by a **local risk assessment** (LRA) and is specific to both the pathogen(s) and the work activities to be performed.

4.4	Personal Protective Equipment	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.4.1	Appropriate dedicated PPE specific to each **containment zone**, to be donned in accordance with entry procedures and to be exclusively worn and stored in the containment zone.	■	■	■	■	■
4.4.2	Face protection to be used where there is a risk of exposure to splashes or flying objects.	■	■	■	■	■
4.4.3	Personnel working in **animal rooms**, animal cubicles, or PM rooms to wear dedicated protective footwear and/or additional protective footwear, as determined by an LRA.	■	■	■	■	■
4.4.4	Gloves to be worn when handling **infectious material**, toxins, or infected animals.	■	■	■	■	■
4.4.5	Full body coverage dedicated protective clothing to be worn inside the **containment barrier** where human or **zoonotic pathogens** are handled.		■	■	■	■

4.4	Personal Protective Equipment	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.4.6	Dedicated protective clothing and footwear to be worn inside the containment barrier where **strict animal pathogens** are handled.			■	■	■
4.4.7	An additional layer of protective clothing to be donned in accordance with entry procedures prior to work with infectious material, toxins, or animals infected with zoonotic pathogens.	P	P	■	■	■
4.4.8	Positive-pressure suits that have passed integrity testing to be worn inside the containment barrier. [*Not required for* ***laboratory work areas*** *where infectious material is exclusively handled in a Class III* ***biological safety cabinet*** *(BSC) line.*]					■
4.4.9	Respirators to be worn where there is a risk of exposure to infectious **aerosols** that can be transmitted through the inhalation route or to aerosolized toxins, as determined by an LRA.		■	■	■	

4.5 Entry and Exit of Personnel, Animals, and Material

The operational practices for entry/exit are critical to maintaining containment integrity and ensuring that only trained and authorized individuals can access the **containment zone**. In **high containment zones**, adherence to operational procedures allows **inward directional airflow** (IDA) to be maintained and keeps contaminated or potentially contaminated **personal protective equipment** (PPE) inside the **containment barrier**. The following matrix presents essential elements for **standard operating procedures** (SOPs) outlining entry and exit procedures.

4.5	Entry and Exit of Personnel, Animals, and Material	CL2	CL2-Ag	CL3	CL3-Ag	CL4
Access and Authorization						
4.5.1	Containment zone, **animal room, animal cubicle**, and **post mortem room** (PM room) doors to be kept closed.	■	■	■	■	■
4.5.2	Access to containment zone to be limited to **authorized personnel** and authorized visitors.	■	■	■	■	■
4.5.3	Authorization to an individual to access a part of the **facility** where **security sensitive biological agents** (SSBAs) are present and accessible to be granted only after confirmation that a valid ***Human Pathogens and Toxins Act* security clearance** (HPTA security clearance) has been issued to that individual.	S	S	■	■	■
4.5.4	An individual's authorization to access a part of a facility where SSBAs are present and accessible to be removed when the individual is no longer in need of access to that part of the facility or when the individual no longer holds a valid HPTA security clearance.	S	S	■	■	■

4.5	Entry and Exit of Personnel, Animals, and Material	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.5.5	Access to supporting mechanical and electrical services for the containment zone to be limited.	■	■			
4.5.6	Access to supporting mechanical and electrical services for the containment zone to be limited and to be kept locked at all times.			■	■	■
4.5.7	Access to areas housing an **effluent decontamination system** to be limited and doors to be kept closed and locked at all times.		P	■	■	■
Entry Procedures						
4.5.8	Current entry requirements to be posted at point(s) of entry to the containment zone, animal rooms, animal cubicles, and PM room.	■	■	■	■	■
4.5.9	Personnel to verify correct reading of monitoring device(s) that visually demonstrate IDA, prior to entry into area where IDA is provided.		■	■	■	■
4.5.10	Personal clothing to be stored separately from dedicated PPE.	■	■	■	■	■
4.5.11	Personal belongings to be kept separate from areas where **infectious material** or **toxins** are handled or stored.	■	■	■	■	■
4.5.12	Personal belongings not required for work to be left outside the containment zone or in change areas outside the containment barrier.	□ P	■	■	■	■

4.5	Entry and Exit of Personnel, Animals, and Material	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.5.13	Personnel to doff personal clothing and footwear and don dedicated clothing and PPE when entering the containment zone.		P	■	■	■
Exit Procedures						
4.5.14	Personnel to doff dedicated PPE, in a manner that minimizes **contamination** of the skin and hair, when exiting the containment zone.	■	■	■	■	■
4.5.15	Personnel to remove gloves and wash hands when exiting the containment zone, animal room, animal cubicle, or PM room.	■	■			
4.5.16	Personnel to remove gloves and wash hands at the containment barrier when exiting the containment zone, animal room, animal cubicle, or PM room.			■	■	
4.5.17	Personnel to doff dedicated PPE (or additional layer of PPE, when worn) when exiting the containment barrier of: • animal cubicles/PM rooms, except when exiting to the dirty corridor; or • the containment zone. [*Not required for CL4 zones where positive-pressure suits are worn.*]	P	■	■	■	■

4.5	Entry and Exit of Personnel, Animals, and Material	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.5.18	Personnel to decontaminate eyeglasses at the containment barrier prior to exit, unless protected from contamination by additional layer of PPE.			■	■	■
4.5.19	Where **non-indigenous animal pathogens** are handled, personnel to remove all clothing and shower out when exiting the containment barrier of the containment zone.			■		
4.5.20	Personnel to remove all clothing and shower out when exiting: • the containment barrier of the animal cubicle/PM room, except when exiting to the dirty corridor; or • the containment barrier of the containment zone.				■	
4.5.21	Personnel wearing positive-pressure suits to proceed through a chemical **decontamination** shower, remove dedicated protective clothing, and remove all clothing and shower out, when exiting the containment barrier.					■

4.6 Work Practices

The use of safe work practices when handling **infectious material** or **toxins** helps protect personnel from **exposure** to **pathogens** and toxins, and helps prevent their **release**. **Good microbiological laboratory practices** are the foundation for all safe work practices involving **biological material**. In **containment zones** where infectious material and toxins are handled or stored, safe work practices include the proper use and maintenance of **biocontainment** systems, **biosafety** equipment (e.g., **biological safety cabinets** [BSCs], centrifuges), as well as aspects of general containment zone maintenance (e.g., tidiness, clutter). Safe work practices documented in **standard operating procedures** (SOPs) can be easily understood and implemented by all personnel.

4.6	Work Practices	CL2	CL2-Ag	CL3	CL3-Ag	CL4
General						
4.6.1	Contact of the face or mucous membranes with items contaminated or potentially contaminated with pathogens or toxins to be prohibited.	■	■	■	■	■
4.6.2	Hair that may become contaminated when working in the containment zone to be restrained or covered.	■	■	■	■	■
4.6.3	Type of footwear worn to be selected to prevent injuries and **incidents**, in accordance with containment zone function.	■	■	■	■	■
4.6.4	Personnel to remove jewellery before entering the containment zone.	P	P	■	■	■
4.6.5	Oral pipetting of any substance to be prohibited.	■	■	■	■	■
4.6.6	Open wounds, cuts, scratches, and grazes to be covered with waterproof dressings.	■	■	■	■	■

4.6	Work Practices	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.6.7	Traffic flow patterns from areas of lower **contamination** (i.e., clean) to areas of higher contamination (i.e., dirty) to be established and followed, as determined by a **local risk assessment** (LRA).	■	■	■	■	■
4.6.8	Dedicated paper/computer work areas to be utilized for paperwork and report writing.	■	■	■	■	■
4.6.9	Use of needles, syringes, and other sharp objects to be strictly limited and avoided when suitable alternatives are available.	■	■	■	■	■
4.6.10	Bending, shearing, re-capping, or removing needles from syringes to be avoided, and, when necessary, performed only as specified in SOPs.	■	■	■	■	■
4.6.11	Work surfaces to be cleaned and decontaminated with a disinfectant effective against the pathogen(s) in use, or a neutralizing chemical effective against the toxin(s) in use, at a frequency to minimize the potential of exposure to infectious material or toxins.	■	■	■	■	■
4.6.12	Personnel trained and able to provide immediate emergency assistance to be available outside the containment zone when work is being conducted.					■
4.6.13	**Verification** of **inward directional airflow** (IDA) to be performed routinely, as described in SOPs. [*Not required for CL2 SA zones.*]	□	■	■	■	■

4.6	Work Practices	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.6.14	Verification of the integrity of **primary containment devices** to be performed routinely, as described in SOPs.	■	■	■	■	■
4.6.15	BSCs, when present, to be certified upon initial installation, annually, and after any repairs, modification, or relocation.	■	■	■	■	■
4.6.16	Operation of containment and life safety systems to be verified daily, as described in SOPs.					■
4.6.17	Integrity of positive-pressure suits to be verified routinely, as described in SOPs.					■
Handling Infectious Material and Toxins						
4.6.18	Good microbiological laboratory practices to be employed.	■	■	■	■	■
4.6.19	Samples of pathogens, toxins, or other regulated infectious material to be opened only in containment zones that meet the **containment level** requirements to which that infectious material or toxin has been assigned.	■	■	■	■	■
4.6.20	Containers of pathogens, toxins, or other regulated infectious material stored outside the containment zone to be labelled, leakproof, impact resistant, and kept either in locked storage equipment or within an area with **limited access**.	■	■			

4.6	Work Practices	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.6.21	Containers of pathogens, toxins, or other regulated infectious material stored outside the containment zone to be labelled, leakproof, impact resistant, and kept in locked storage equipment and within an area with limited access.	P	P	■	■	
4.6.22	Containers of **security sensitive biological agents** (SSBAs) stored outside the containment zone to be labelled, leakproof, impact resistant, and kept in locked storage equipment that is fixed in place (i.e., non-movable).	S	S	■	■	
4.6.23	Pathogens, toxins, and other regulated infectious material to be stored inside the containment zone.					■
4.6.24	A certified BSC to be used for procedures involving open vessels of infectious material or toxins that: • may produce infectious **aerosols** or aerosolized toxins, when aerosol generation cannot be contained through other methods; • involve **high concentrations** of infectious material or toxins; or • involve **large volumes** of infectious material or toxins. [*Not required when collecting samples from or inoculating animals housed in an* ***animal cubicle***.]	■	■			

4.6	Work Practices	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.6.25	All activities involving open vessels of infectious material or toxins to be performed in a certified BSC or other appropriate primary containment device. [*Not required when collecting samples from or inoculating animals housed in an animal cubicle.*]			■	■	■
4.6.26	Procedures to be followed to prevent the inadvertent spread of contamination from items removed from the BSC after handling infectious material or toxins.	■	■	■	■	■
4.6.27	Personnel to wash hands after completing tasks that involve the handling of infectious material or toxins and before undertaking other tasks in the containment zone.	■	■	■	■	
4.6.28	Centrifugation of infectious material where inhalation is the primary route of infection to be carried out in sealed safety cups (or rotors) that are unloaded in a BSC.	■	■			
4.6.29	Centrifugation of infectious material to be carried out in sealed safety cups (or rotors) that are unloaded in a BSC.	P	P	■	■	■
4.6.30	Use of on-demand open flames in a BSC to be strictly limited and avoided when suitable alternatives are available; sustained open flames to be prohibited in a BSC.	■	■	■	■	■

4.6	Work Practices	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.6.31	Procedures, as determined by an LRA, to be in place to prevent a leak, drop, spill, or similar event during the **movement** of infectious material or toxins within the containment zone or between containment zones within a building.	■	■	■	■	■
4.6.32	**Large scale cultures** of infectious material or toxins to be contained within a **closed system** or other primary containment device. [*Not required for CL2 SA zones.*]	□		■		■
4.6.33	Collecting samples, adding materials, or transferring culture fluids from one closed system to another to be performed in a manner that prevents the release of aerosols or the contamination of exposed surfaces.	■	■	■	■	■
4.6.34	Experimentally infecting cells or other specimens derived from the person conducting the experiment to be prohibited.	■	■	■	■	■
Housekeeping and General Maintenance						
4.6.35	Containment zone (including floors) to be kept clean, free from obstructions, and free from materials that are in excess, not required, or that cannot be easily decontaminated.	■	■	■	■	■
4.6.36	Routine cleaning, as described in SOPs, to be carried out by containment zone personnel or other staff trained specifically for this task.	□ P	■	■	■	■

4.6	Work Practices	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.6.37	An effective rodent and insect control program to be maintained.	■	■	■	■	■
4.6.38	Water seals in drainage traps to be maintained through regular usage or filling.			■	■	■
4.6.39	An acceptable mechanism to be utilized for the safe removal of **high efficiency particulate air (HEPA) filters**.	■	■	■	■	■
4.6.40	A basic tool kit to be available inside the containment zone.			■	■	■

4.7 Animal Work Considerations

Due to their unpredictable behaviour, especially when ill, ***in vivo*** work with **pathogens** and **toxins** involving live animals increases the **risk** associated with any given procedure. In addition, **large volumes** of contaminated **waste** are generated in animal **containment zones**. Special considerations and handling techniques for work with animals help prevent personnel **exposure** or **release** of pathogens or toxins where animals are infected or potentially infected with **zoonotic pathogens**, or are asymptomatic carriers of human pathogens. Safe work practices for animal work considerations documented in **standard operating procedures** (SOPs) can be easily understood and implemented by all personnel.

4.7	Animal Work Considerations	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.7.1	Proper methods of restraint to be used to minimize scratches, bites, kicks, crushing injuries, and accidental self-inoculation. [*Not required for CL2* ***large scale*** *production areas.*]	□	■	■	■	■
4.7.2	**Primary containment caging** housing infected animals to be identified with labels. [*Not required for CL2 large scale production areas.*]	□		■		■
4.7.3	Handling procedures to be employed to minimize the creation of **aerosols** and dissemination of dust from cages, refuse, and animals. [*Not required for CL2 large scale production areas.*]	□	■	■	■	■
4.7.4	Entry/exit procedures to be employed to minimize the release of aerosolized or **airborne pathogens** from **animal cubicles** and **post mortem rooms** (PM rooms).		■		■	■

4.7	Animal Work Considerations	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.7.5	Animals and carcasses to be securely moved into, out of, and within the containment zone. [*Not required for CL2 large scale production areas.*]	□	■	■	■	■
4.7.6	Animal carcasses to be removed from cubicles/PM rooms via the dirty corridor, or if removed via the clean corridor, to be divided into smaller portions (as necessary) and placed into labelled, leakproof, and impact resistant transport containers.		■		■	■
4.7.7	Inoculation, surgical, and necropsy procedures to be designed and carried out to prevent injuries to personnel and minimize the creation of aerosols. [*Not required for CL2 large scale production areas.*]	□	■	■	■	■
4.7.8	Inoculation, surgical, and necropsy procedures with animals in **small animal containment zones** (SA zones) to be carried out in a certified **biological safety cabinet** (BSC) or other appropriate **primary containment device**. [*Not required for CL2 large scale production areas.*]	□		■		■
4.7.9	Animals to be disinfected and/or cleaned at site of injection or exposure following inoculation or aerosol challenge with **infectious material** or toxins. [*Not required for CL2 large scale production areas.*]	□	■	■	■	■

4.8 Decontamination and Waste Management

Effective **decontamination** of **waste** is critical in all **containment zones** so that contaminated material is treated and safely disposed of. The principles of **sterilization, disinfection**, and decontamination are essential for reducing the **risk** of **pathogen** and **toxin** transmission within containment zones, or **release** to the environment or the **community**. Decontamination and waste management procedures documented in **standard operating procedures** (SOPs) can be easily understood and implemented by all personnel.

4.8	Decontamination and Waste Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.8.1	**Gross contamination** to be removed prior to decontamination of surfaces and equipment, and disposed of accordingly.	■	■	■	■	■
4.8.2	Disinfectants effective against the pathogen(s) in use and neutralizing chemicals effective against the toxin(s) in use to be available and used in the containment zone.	■	■	■	■	■
4.8.3	Sharps to be discarded in containers that are leakproof, puncture-resistant, and fitted with lids, or specially constructed for the disposal of sharps waste.	■	■	■	■	■
4.8.4	**Primary containment devices** to be decontaminated prior to maintenance.	■	■	■	■	■
4.8.5	All clothing and **personal protective equipment** (PPE) to be decontaminated when a known or suspected **exposure** has occurred.	■	■	■	■	■
4.8.6	PPE to be decontaminated prior to disposal or laundering unless laundering **facilities** are located within the containment zone and have been proven to be effective in decontamination.	P	■	■	■	■

4.8	Decontamination and Waste Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.8.7	Contaminated liquids to be decontaminated prior to release to sanitary sewers.	■	■	■	■	■
4.8.8	Contaminated equipment, materials, and waste to be: • decontaminated and labelled as decontaminated prior to cleaning, disposal, or removal from the containment zone or prior to removal from the **animal rooms, animal cubicles**, or **post mortem rooms** (PM rooms), as described in SOPs; or • placed in closed, labelled, and leakproof containers that have been surface decontaminated prior to removal from the containment zone, animal rooms, animal cubicles, or PM rooms, as described in SOPs for the safe and secure **movement** or **transportation** to a designated decontamination area or storage outside of the containment zone.	■	■			
4.8.9	All equipment, materials, and waste to be decontaminated at the **containment barrier** and labelled as decontaminated prior to removal from the containment zone and prior to removal from the animal rooms, animal cubicles, or PM rooms.			■	■	■
4.8.10	**Decontamination technologies** and processes to be validated prior to initial use and when significant changes to the processes are implemented or new pathogens are introduced.	■	■	■	■	■

4.8	Decontamination and Waste Management	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.8.11	Decontamination technologies and processes to be routinely verified, as described in SOPs. Frequency of **verification** to be determined by a **local risk assessment** (LRA).	■	■	■	■	■
4.8.12	Doors of **pass-through technologies** not to be opened simultaneously.			■	■	■
4.8.13	Contaminated bedding to be: • removed at a **ventilated cage changing station** or within a certified **biological safety cabinet** (BSC) prior to decontamination; or • decontaminated within containment cages.	■		■		■
4.8.14	Animal cubicles, PM rooms, and dirty corridor, when present, to be decontaminated when grossly contaminated and at the end of an experiment.		■		■	■
4.8.15	Procedures for full room decontamination to be developed, validated, and followed, as determined by an LRA.	P	P	■	■	■

4.9 Emergency Response

In order to promote personnel safety and the containment of **pathogens** and **toxins**, plans need to be in place for situations where **biosafety** or **biosecurity** issues may arise as the result of an emergency. Emergency situations may include **incidents** or **accidents**, medical emergencies, fire, chemical or biological spills, power failure, animal escape, failure of **primary containment devices** (e.g., **biological safety cabinet** [BSC]), loss of containment (e.g., heating, ventilation, and air conditioning [HVAC]), and natural disasters. Protocols for incident reporting and investigation are an integral component of an **emergency response plan** (ERP) as incidents may be indicative of deficiencies in biosafety and/or biosecurity systems.

4.9	Emergency Response	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.9.1	The ERP is to describe emergency procedures applicable to the **containment zone** for: • accidents/incidents; • medical emergencies; • fires; • chemical/biological spills (small/large; inside/outside BSC and centrifuge); • power failure; • animal escape (if applicable); • failure of primary containment devices; • **puff-back** from class II B2 BSCs, where present; • loss of containment; • emergency egress; • notification of key personnel and relevant federal regulatory agency (or agencies); • natural disasters; and • incident follow-up and recommendations to mitigate future **risks**.	■	■	■	■	■
4.9.2	ERP to include procedures for any **infectious material** or toxins stored outside the containment zone.	■	■	■	■	

4.9	Emergency Response	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.9.3	ERP to include procedures for positive-pressure suit damage, loss of breathing air, and loss of chemical **decontamination** shower.					■
4.9.4	ERP to include additional exit procedures to describe emergency scenarios where showering out of the containment zone is necessary.			■		
4.9.5	ERP to include additional emergency egress procedures for life-threatening emergencies.			■	■	■
4.9.6	A biological spill kit to be available inside the containment zone.	P	P	■	■	■
Incident Investigation and Reporting						
4.9.7	Incidents involving pathogens, toxins, other regulated infectious material, infected animals, or involving failure of **containment systems** or control systems to be reported immediately to the appropriate internal authority.	■	■	■	■	■
4.9.8	Incident investigation to be conducted and documented for any incident involving pathogens, toxins, other regulated infectious material, infected animals, or failure of containment systems or control systems, in order to determine the root cause(s).	■	■	■	■	■

4.9	Emergency Response	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.9.9	The Public Health Agency of Canada (PHAC) to be informed without delay via the submission of an **exposure notification report** following: • an exposure to a human pathogen or toxin; or • recognition of a disease that has or may have been caused by an exposure to a human pathogen or toxin.	■	■	■	■	■
4.9.10	An **exposure follow-up report** documenting the completed investigation, to be submitted to the PHAC within: • 15 days of the submission of an exposure notification report involving a **security sensitive biological agent** (SSBA); or • 30 days of the submission of an exposure notification report involving a human pathogen or toxin other than an SSBA.	■	■	■	■	■

4.10 Records and Documentation

A **biosafety** program will generate records for most activities. These records provide evidence that a specific activity was performed, document the results achieved, and can also be used for the ongoing improvement of the biosafety program.

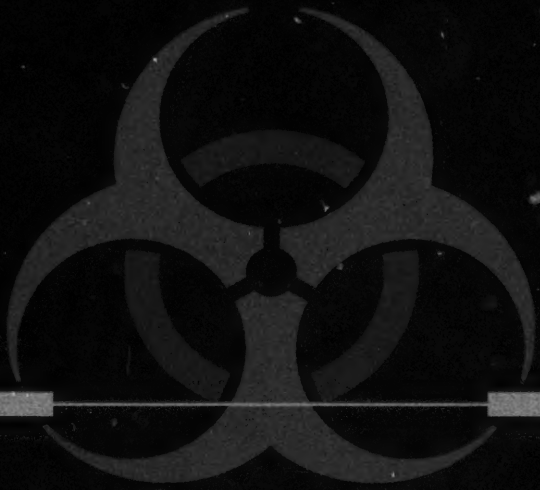
4.10	Records and Documentation	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.10.1	Training and refresher training to be documented; records to be kept on file.	■	■	■	■	■
4.10.2	**Inventory** of **pathogens, toxins**, and other regulated **infectious material** in **long-term storage** to be maintained, including location and **risk group**(s). Inventory to include pathogens, toxins, and other regulated infectious material stored outside of the **containment zone**.	■	■	■	■	■
4.10.3	Inventory of Risk Group 3 (RG3) and Risk Group 4 (RG4) pathogens and **security sensitive biological agent** (SSBA) toxins in long-term storage, both inside and outside the containment zone, to be maintained and to include: • specific identification of the pathogens, toxins, and other regulated infectious material; and • a means to allow for the detection of a missing or stolen sample in a timely manner.	S	S	■	■	■
4.10.4	Drawings and physical specifications (including "as built" drawings of all structures and services pertaining to the containment zone) and reports of performance and **verification** tests of **containment systems** to be kept on file. [*Not required for SA zones.*]	□ P	P	■	■	■

4.10	Records and Documentation	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.10.5	Records of regular inspections of the containment zone and corrective actions to be kept on file.	■	■	■	■	■
4.10.6	Records of building and equipment maintenance, repair, inspection, testing, or certification, including performance verification and testing records, in accordance with containment zone function, to be kept on file.	■	■	■	■	■
4.10.7	Equipment used for performance verification and testing of containment systems and essential biosafety equipment to have a valid calibration certificate at the time of testing; calibration certificates to be kept on file.	■	■	■	■	■
4.10.8	A record of all individuals entering and exiting the containment zone to be maintained and kept on file.	S	S	■	■	■
4.10.9	Records of **validation** and routine verification of **decontamination technologies** and processes to be kept on file.	■	■	■	■	■

4.10	Records and Documentation	CL2	CL2-Ag	CL3	CL3-Ag	CL4
4.10.10	Records and documentation pertaining to: • **licence** activities involving human pathogens and toxins to be kept on file for a minimum of 5 years; and • **animal pathogen import permit** requirements for **animal pathogens**, toxins, and other regulated infectious material to be kept on file for a minimum of 2 years following the date of disposal, complete **transfer**, or inactivation of the imported material.	■	■	■	■	■
4.10.11	Records of **incidents** involving pathogens, toxins, other regulated infectious material, infected animals, or losses of containment to be kept on file for a minimum of 10 years.	■	■	■	■	■
4.10.12	Access to records and documentation pertaining to **controlled activities** with human pathogens and toxins to be restricted to **authorized personnel**.	S	S	■	■	■

CHAPTER 5

PERFORMANCE AND VERIFICATION TESTING REQUIREMENTS



CHAPTER 5 – PERFORMANCE AND VERIFICATION TESTING REQUIREMENTS

The requirements presented in Matrices 5.1 through 5.3 describe the minimum performance and **verification** tests necessary to demonstrate compliance with the **physical containment requirements** outlined in Chapter 3 and, in some cases, with the **operational practice requirements** outlined in Chapter 4. Reports demonstrating the successful completion of these tests are requested by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) in support of applications for a **licence** for **controlled activities** with human **pathogens** and **toxins**, applications for an **animal pathogen import permit**, or **facility certification** (or recertification) of **containment zones**. In addition, test reports will be monitored by the PHAC and the CFIA for ongoing compliance verification, including during on-site inspections and audits. The corresponding physical containment and operational practice requirements from Chapters 3 and 4 are referenced in the individual explanatory note (found in the Appendix) for each requirement in Matrices 5.1-5.3. The **containment level** columns indicate the containment levels to which each requirement applies. In certain scenarios, the PHAC or the CFIA may request additional tests, on a case-by-case basis, to demonstrate performance or verification of **containment systems** other than those tests described in the matrices below. A description of the symbols used appears in Section 2.6.

5.1 Performance and Verification Tests for All Containment Levels

The following matrix describes the minimal performance and **verification** tests to be performed by all types of work areas at all **containment levels** (CL2-CL4).

5.1	Performance and Verification Tests for All Containment Levels	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.1.1	Performance and verification tests described in 5.1.2-5.1.7 to be conducted and documented at minimum annually, or more frequently as indicated by: • a change, repair, or modification to the **containment system**; • a condition of **licence**; or • a request of the Public Health Agency of Canada (PHAC) or the Canadian Food Inspection Agency (CFIA).	■	■	■	■	■

5.1	Performance and Verification Tests for All Containment Levels	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.1.2	Visual inspections of the **containment zone** to be conducted in order to identify faults and/or deterioration; when found, corrective actions to be taken.	■	■	■	■	■
5.1.3	Visual inspections of small in-line filters to be conducted and filters to be replaced in accordance with maintenance schedules or as necessary to maintain function.	■	■	■	■	■
5.1.4	**Decontamination technology** and processes to be validated through the use of **representative loads** in conjunction with application-specific biological indicators, chemical integrators, and/or parametric monitoring devices consistent with the technology/method.	■	■	■	■	■
5.1.5	Class II **biological safety cabinets** (BSCs) to be certified in accordance with NSF/ANSI 49, where possible.	■	■	■	■	■

5.1	Performance and Verification Tests for All Containment Levels	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.1.6	Verification of the following manufacturer's specifications to be demonstrated, where the design of a BSC or custom ventilated enclosure does not permit certification in accordance with NSF/ANSI 49: • integrity of the **high efficiency particulate air (HEPA) filters** to be tested in accordance with the HEPA filter test method IEST-RP-CC034.3 or equivalent; • maintenance of a minimum average inflow velocity of 0.38 m/s (75 ft/min) through the front opening during normal operation to be verified; • airflow pattern inside the cabinet and at access opening to ensure no back streaming of air to be demonstrated; • integrity of BSCs designed with positive-pressure plenums to be demonstrated by determining that exterior surfaces of all plenums, welds, gaskets, and plenum penetrations or seals, are free of leaks (to be performed during initial installation, if any panels are removed, or if the cabinet is relocated); and • alarms to be demonstrated to function as intended.	■	■	■	■	■
5.1.7	Integrity of **primary containment devices** other than BSCs (e.g., **process equipment, closed systems, primary containment caging**) to be tested in accordance with testing procedures and acceptance criteria appropriate for the equipment and design.	■	■	■	■	■

5.2 Additional Performance and Verification Tests for Select CL2 and CL2- Ag Zones and All CL3-CL4 Zones

In addition to the performance and **verification** tests to be performed for all **containment zones** outlined in Matrix 5.1, the following matrix describes the additional performance and verification tests to be performed by any containment zone at all **containment levels** CL2-CL4, with the exception of CL2 **laboratory work areas** and CL2 SA zones, unless, as indicated, **prions** or **security sensitive biological agents** (SSBAs) are handled in these work areas.

5.2	Additional Performance and Verification Tests for Select CL2 and CL2-Ag Zones and All CL3-CL4 Zones	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.2.1	Performance and verification tests described in 5.2.3-5.2.11 to be conducted and documented at minimum every two years, or more frequently, where specified or as indicated by: • a change, repair, or modification to the **containment system**; • a condition of **licence**; • a condition of **animal pathogen import permit**; or • a request of the Public Health Agency of Canada (PHAC) or the Canadian Food Inspection Agency (CFIA). [*Does not apply where SSBAs are present.*]	☐ P	■			
5.2.2	Performance and verification tests described in 5.2.3-5.2.15 to be conducted and documented at minimum annually, or more frequently as indicated by: • a change, repair, or modification to the containment system; • a condition of licence; or • a request of the PHAC or the CFIA.	S	S	■	■	■

5.2	Additional Performance and Verification Tests for Select CL2 and CL2-Ag Zones and All CL3-CL4 Zones	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.2.3	Operation of **controlled access systems** and security systems to be verified to be functioning as intended. [*Not required in CL2 SA zones where Prions and SSBAs are not present.*]	☐ PS	■	■	■	■
5.2.4	Emergency power and uninterrupted power supply (UPS) systems to be tested under representative electrical load conditions. [*Not required in CL2 SA zones where Prions and SSBAs are not present.*]	☐ PS	■	■	■	■
5.2.5	Operation of communication systems to be verified. [*Not required in CL2 SA zones where Prions are not present.*]	☐ P	■	■	■	■
5.2.6	Integrity of penetrations of the **containment barrier**, seals, and surfaces, to be visually inspected. [*Not required in CL2 SA zones where Prions are not present.*]	☐ P	P	■	■	■
5.2.7	Testing to be performed at all **critical doors** on the containment barrier, where **inward directional airflow** (IDA) is provided, to verify, using a smoke pencil or other visual aid that does not influence the direction of airflow, that IDA is maintained in accordance with **facility** design. [*Not required in CL2 SA zones.*]	☐	■	■	■	■

5.2	Additional Performance and Verification Tests for Select CL2 and CL2-Ag Zones and All CL3-CL4 Zones	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.2.8	**High efficiency particulate air (HEPA) filters** to be tested ***in situ*** by particle challenge testing using the scanning method in accordance with IEST-RP-CC034.3 or IEST-RP-CC006.3. When scan testing is not possible, probe testing is acceptable.	□	■	■	■	■
5.2.9	Operation of mechanical or electronic door **interlocks** and associated manual overrides to be verified.		■	■	■	■
5.2.10	**Decontamination technology** alarms to be verified to function as intended.		P	■	■	■
5.2.11	Water supply backflow preventers to be tested at minimum annually in accordance with CAN/CSA B64.10/B64.10.1.		P	■	■	■
5.2.12	Integrity of the seals of containment barrier penetrations, **animal cubicle** penetrations, and **post mortem room** (PM room) penetrations to be tested with a smoke pencil or other aid that does not influence the direction of airflow.		■	■	■	■
5.2.13	Compressed breathing air and systems to be verified in accordance with CAN/CSA-Z180.1. [*Not required for CL4 laboratory work areas where* ***infectious material*** *is exclusively handled in a Class III* ***biological safety cabinet*** *(BSC) line.*]					■

5.2	Additional Performance and Verification Tests for Select CL2 and CL2-Ag Zones and All CL3-CL4 Zones	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.2.14	Positive-pressure suits to be tested to ensure operation in accordance with manufacturer's specifications. [*Not required for CL4 laboratory work areas where infectious material is exclusively handled in a Class III BSC line.*]					■
5.2.15	Chemical **decontamination** shower systems, including the disinfectant tank low level alarm and parametric monitoring and recording devices, to be verified to function as intended. [*Not required for CL4 laboratory work areas where infectious material is exclusively handled in a Class III BSC line.*]					■

5.3 Performance and Verification Tests to be Conducted on Commissioning of Containment Zone

In addition to the performance and **verification** tests to be performed outlined in Matrices 5.1 and 5.2, the following matrix describes the performance and verification tests to be performed by any **containment zone** at the indicated **containment levels** upon **commissioning** of the containment zone. Test reports documenting successful completion of these tests will be requested by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) for a newly commissioned containment zone to support an application for a new **licence** for **controlled activities** with human **pathogens** and **toxins**, for an application for an **animal pathogen import permit** for a containment zone that has not previously imported an **animal pathogen**, or for the initial **facility certification** for a containment zone intending to conduct activities with **non-indigenous animal pathogens**. Retesting of the **containment system**(s) is indicated by a change, repair, or modification to the containment device or system; a condition of licence; or a request of the PHAC or the CFIA.

5.3	Performance and Verification Tests to be Conducted on Commissioning of Containment Zone	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.3.1	Drain piping leading to an **effluent decontamination system** to be tested in accordance with the *National Plumbing Code of Canada*. Air test on drainage system to be performed at standard code pressure specifications of 35,000 Pa (i.e., 141 inches of water gauge [in. w.g.]).		P	■	■	■
5.3.2	Integrity of **high efficiency particulate** air (HEPA) filter housings to be tested ***in situ*** by **pressure decay** in accordance with ASME N511; test pressure to be determined in accordance with ASME AG-1. Acceptance criteria include the provision that the rate of leakage is not to exceed 0.1% of volume/minute at 1,000 Pa (i.e., 4 inches water gauge [in. w.g.]) minimum test pressure.			■	■	■

5.3	Performance and Verification Tests to be Conducted on Commissioning of Containment Zone	CL2	CL2-Ag	CL3	CL3-Ag	CL4
5.3.3	Heating, ventilation, and air conditioning (HVAC) system and controls to be verified during scenarios simulating failure of system components, including exhaust fan(s), supply fan(s), power, and Class II B2 **biological safety cabinet** (BSC) exhaust fan(s) (where present), as determined by containment zone design. Acceptance criteria include demonstration that reversal of **inward directional airflow** (IDA) is not sustained at **critical doors**; Class II B2 BSC **puff-back** is minimized, and HVAC system alarms and interlocks operate as intended.			■	■	■
5.3.4	Supply ductwork, located between **backdraft protection** and containment barrier, and exhaust ductwork, located between containment barrier and HEPA filter or **isolation damper**, to be visually inspected and tested *in situ* by pressure decay in accordance with ASME N511; test pressure to be determined in accordance with ASME AG-1. Acceptance criteria include the provision that the rate of leakage is not to exceed 0.1% of volume/minute at 1,000 Pa (i.e., 4 in. w.g.) minimum test pressure.			■	■	■
5.3.5	Integrity of containment barrier to be tested by pressure decay testing. Acceptance criteria include two consecutive tests with a maximum of 250 Pa (i.e., 1 in. w.g.) loss of pressure from an initial 500 Pa (i.e., 2 in. w.g.) over a 20 minute period. [*Not required in CL3-Ag zones where only human and/or indigenous animal pathogens are handled.*]				■	■

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REFERENCES

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APPENDIX

APPENDIX – EXPLANATORY NOTES

The following table provides additional information pertaining to the physical containment, operational practice, and performance and verification testing requirements outlined in Chapters 3, 4, and 5, respectively. Specifically, these notes include a brief explanation of the risk(s) mitigated by a requirement and typical examples of how the requirement may be achieved. Further guidance on the subjects can be found in the *Canadian Biosafety Handbook*, 2nd Edition.

Requirement Number(s)	Explanatory Note
3.1.1	A door is a physical barrier that protects against the release of infectious material or toxins by separating the containment zone (i.e., the "dirty" or contaminated area) from public and administrative areas (i.e., "clean" or uncontaminated areas) while also providing a security barrier to limit access to the zone.
3.1.2	Separating dedicated containment zone paper/computer work stations from benches and other areas where infectious material and toxins are actively handled minimizes the risk of contamination of office materials which may be difficult to decontaminate (e.g., paper, notebooks) or may become damaged by decontamination (e.g., electronic devices). This can be achieved by locating these stations in a dedicated room within the containment zone, by installing a physical partition (e.g., splash shield) between a paperwork station adjacent to a laboratory bench, or by locating paper/computer work stations in a space inside the containment zone but at a distance from benches.
3.1.3	The design and choice of materials used for walls, ceilings, floors, and barrier devices are critical for ensuring that the containment zone has the structural stability to withstand both internal stresses, such as the negative or positive pressures that result from a failure of the supply air or exhaust air fan, and external stresses, such as external weather conditions (e.g., temperature extremes, humidity, wind), environmental disasters (e.g., tornado, earthquake), and security threats (e.g., break-in, theft). This is best achieved at the design stage by locating the containment zone away from external envelope walls and choosing construction materials in accordance with anticipated function of the zone.

Requirement Number(s)	Explanatory Note
3.1.4	Separating laboratory work areas inside LA zones from spaces where animals are housed (i.e., animal cubicles) prevents contamination of work materials not associated with animal work. This can be achieved by designing the animal containment zone to include a laboratory work area for activities that do not directly involve the animals (e.g., preparing samples or inoculants).
3.1.5	Cold storage equipment located in, or adjacent to, the PM room is important to protect against the putrefaction of animal carcasses during temporary storage while awaiting necropsy or disposal. This can be achieved by including an integral cold room (suitable for large-sized animals) or installing a refrigerator or freezer of adequate size.
3.2.1	Basic pest control and security measures on windows that can open protect against the entry of small-sized animals and insects and prevent the release of infectious material out of the containment zone, especially where the window opens directly to the outdoors. This can be achieved by fitting windows with properly installed screens that are in good repair and by closing and locking windows to prevent unauthorized entry, in particular, when the containment zone is unoccupied.
3.2.2	Keeping windows on the containment barrier that can open locked in a closed position protects against unauthorized entry to the containment zone.
3.2.3	Sealed windows protect against unauthorized entry and maintain the air pressure differentials in containment zones where IDA is provided.
3.2.4	Glazing materials, such as double-glazed windows, tempered glass, wire glass, heat or chemically strengthened glass, laminated safety glass, acrylic glazing, polycarbonate glazing, and adhesive window security films, provide various degrees of protection against breakage, security threats, or environmental threats.
3.2.5	Windows located on the containment barrier that allow the public to see into animal rooms, animal cubicles, or PM rooms pose a biosecurity risk and compromise animal well-being.

Requirement Number(s)	Explanatory Note
3.2.6	Ensuring that equipment on the containment barrier maintains a continuous seal with the adjacent wall, ceiling, or floor protects the integrity of the containment barrier and protects against the inadvertent release of infectious material or toxins. A bioseal (i.e., a biological sealing flange or gasket made of flexible material that surrounds the body of the barrier autoclave or other equipment on the containment barrier and creates a hermetic seal between the clean and dirty sides of the containment zone) is an example of a treatment that can be used to create a seal around a barrier autoclave or other equipment that penetrates the containment barrier.
3.2.7	Preventing the simultaneous opening of doors on both sides of pass-through technologies prevents a containment breach and the release of infectious material or toxins from the containment zone. Examples of suitable mechanisms at CL3 include mechanical or electronic door interlocks, visual or audible alarms, or SOPs preventing personnel from opening doors simultaneously.
3.2.8	Preventing the simultaneous opening of doors on both sides of pass-through technologies prevents a containment breach and the release of infectious material or toxins from the containment zone. Examples of suitable mechanisms at CL3-Ag include mechanical or electronic door interlocks.
3.2.9	Preventing the simultaneous opening of doors on both sides of pass-through technologies prevents a containment breach and the release of infectious material or toxins from the containment zone. A backup mechanism is included at CL4 to provide added protection. Examples of suitable mechanisms at CL4 include mechanical or electronic door interlocks, and visual or audible alarms to prevent personnel from opening doors simultaneously.

Requirement Number(s)	Explanatory Note
3.2.10	Penetrations of the containment barrier at or below the work surface and any other surface that may become contaminated (e.g., conduits, plumbing, and wiring) may leave gaps between the penetration and the surface of the containment barrier that could allow the inadvertent release of infectious material. Sealing these gaps with sealants that are non-shrinking and compatible with the chemical disinfectants in use (e.g., silicone, polyurethane, or polyether caulking) allows for proper spill cleanup and surface decontamination, and maintains the integrity of the containment barrier.
3.2.11	Penetrations of the containment barrier (e.g., dunk tanks, pass-through chambers, conduits, plumbing, and wiring) may leave gaps between the penetration and the surface of the containment barrier that could allow the inadvertent release of infectious material. Sealing these gaps with sealants that are non-shrinking and compatible with the chemical disinfectants in use (e.g., silicone, polyurethane, or polyether caulking) allows for proper spill cleanup and surface decontamination, and maintains the integrity of the containment barrier.
3.2.12	Penetrations of the containment barrier of animal cubicles and PM room (e.g., dunk tanks, pass-through chambers, conduits, plumbing, and wiring) may leave gaps between the penetration and the surface of the containment barrier that could allow the inadvertent release of infectious material. Sealing these gaps with sealants that are non-shrinking and compatible with the chemical disinfectants in use (e.g., silicone, polyurethane, or polyether caulking) allows for proper spill cleanup and surface decontamination, and maintains the integrity of the containment barrier.
3.3.1	Lockable doors provide a basic security barrier to prevent unauthorized access to the containment zone and to safeguard the infectious material and toxins stored inside.

Requirement Number(s)	Explanatory Note
3.3.2	Biohazard warning signage is a critical messaging tool designed to advise that infectious material or toxins are present in the containment zone, to indicate any special entry requirements, and to provide contact information in case of an emergency.
3.3.3	Project-specific signage posted at the point(s) of entry for animal rooms, animal cubicles, and PM rooms is an important messaging tool to inform of any special entry requirements for a particular experiment or study where hazards unique to a room or cubicle exist (i.e., the same hazard is not present in the other adjoining rooms within the containment zone).
3.3.4	Controlled access systems are used to provide restricted access to the part of the containment zone where SSBA are present and accessible to authorized individuals only, and to maintain the security of that part of the containment zone at all times (i.e., locked at all times) when SSBA are present and accessible (including when vacant and during emergency evacuation situations). Examples of controlled access systems include biometric readers, electronic access card systems, keypads, key code systems, key-locks with non-reproducible keys, or an equivalent system.
3.3.5	Controlled access systems are used to provide restricted access to the containment zone to authorized individuals and to maintain the security of the containment zone at all times (including when vacant and during emergency evacuation situations). Examples of controlled access systems include biometric readers, electronic access card systems, keypads, key code systems, key-locks with non-reproducible keys, or an equivalent system.
3.3.6	Controlled access systems are used to provide restricted access to animal cubicles and PM rooms to authorized individuals and to maintain the security of those areas at all times (including when vacant and during emergency evacuation situations). Examples of controlled access systems include biometric readers, electronic access card systems, keypads, key code systems, key-locks with non-reproducible keys, or an equivalent system. Physical systems are preferred over other mechanisms to restrict access.

Requirement Number(s)	Explanatory Note
3.3.7	Keys that cannot be reproduced without the authorization of the containment zone director, supervisor, manager, or other delegated individual (as determined by the organization) protects against unauthorized entry and restricts access to the containment zone to only authorized personnel to whom keys have been issued.
3.3.8	Providing backup to a controlled access system maintains the security of the containment zone, even in the event of a power failure or emergency release of electronic locking systems. Examples of alternate controlled access systems include a physical key code system or key-locks with non-reproducible keys.
3.3.9	Dedicated storage space is necessary to store the PPE used in the containment zone (e.g., lab coat, coveralls, face shields, respirators) and to separate these items from personal clothing (e.g., coats, hats, boots) in order to prevent contamination. Hooks, lockers, shelves, or spaces within dedicated change areas are examples of dedicated storage space for PPE.
3.3.10	Dedicated clothing change areas at the entry and exit to the containment zone provide the space necessary to don and doff dedicated PPE, including protective clothing, used inside the containment zone and protect: against the contamination of personal clothing. The clothing change areas may be an anteroom, part of an anteroom, or, in some cases, a designated area at the entry and exit of the containment zone that is separated into a "clean" change area and "dirty" change area by a line demarcating the "clean" and "dirty" areas.
3.3.11	The presence of an anteroom (or anterooms) at the point(s) of personnel entry to and exit from a containment zone creates a buffer space to maintain IDA created through the negative air pressure differentials and prevents the migration of potentially contaminated air to an area of lower contamination or lower containment (i.e., outside the containment barrier or outside the containment zone). This may be achieved by a single anteroom for entry and exit for the containment zone or multiple anterooms dedicated for the entry and exit of personnel separate from the entry and exit of animals or equipment, as determined by the function and activities of the containment zone.

Requirement Number(s)	Explanatory Note
3.3.12	The presence of an anteroom (or anterooms) at the point(s) of personnel entry to and exit from a containment zone or each animal cubicle and PM room creates a buffer space to maintain IDA created through the negative air pressure differentials and prevent the migration of potentially contaminated air to an area of lower contamination or lower containment (i.e., outside the containment barrier of the animal cubicle or PM room, or outside the containment zone). This may be achieved by a single anteroom for entry and exit for the containment zone or multiple anterooms dedicated for the entry and exit of personnel separate from the entry and exit of animals or equipment, as determined by the function and activities of the containment zone.
3.3.13	The presence of an anteroom (or anterooms) at the point(s) of personnel entry to and exit from a containment zone and each animal cubicle and PM room creates a buffer space to maintain IDA created through the negative air pressure differentials and prevents the migration of potentially contaminated air to an area of lower contamination or lower containment (i.e., outside the containment barrier of the animal cubicle or PM room, or outside the containment zone). This may be achieved by a single anteroom for entry and exit for the containment zone or multiple anterooms dedicated for the entry and exit of personnel separate from the entry and exit of animals or equipment, as determined by the function and activities of the containment zone.
3.3.14	A walk-through body shower, located on the containment barrier of the containment zone between the "clean" and "dirty" change areas in the anterooms, allows personnel to wash their hair and body to remove any potential contamination before exiting the containment zone. The body shower is considered to be an extension of the "dirty" change area, and is inside the containment barrier.
3.3.15	A walk-through body shower, located on the containment barrier of the containment zone and another located on the containment barrier of each animal cubicle and PM room, between the "clean" and "dirty" change areas in the respective anterooms, allows personnel to wash their hair and body to remove any potential contamination before exiting the containment barrier of the animal cubicle, PM room, or containment zone. The body shower is considered to be an extension of the "dirty" change area, and is inside the containment barrier.

Requirement Number(s)	Explanatory Note
3.3.16	In CL4 zones where personnel wear positive-pressure suits, a chemical shower (or suit decontamination shower) is a critical safety feature to be included in the "dirty" change area of the anteroom to decontaminate the suit before it is removed. The location of the chemical shower in the exit sequence is critical to prevent exposure of personnel. The chemical shower is located at the immediate exit from the contaminated area, followed by the designated suit change area(s) (i.e., "dirty" change areas where the decontaminated suit is removed), then by the walk-through body shower(s) on the containment barrier which allows personnel to wash their hair and body to remove any potential contamination, and, finally, by "clean" change area(s) just before the exit from the containment zone. The chemical decontamination shower, suit change area, and walk-through body shower are considered to be an extension of the "dirty" area within the anteroom, and are inside the containment barrier.
3.3.17	Preventing the simultaneous opening of anteroom critical door(s) with adjacent and sequential anteroom doors maintains the negative air pressure differentials and limits the migration of potentially contaminated air into the "clean" change area or outside the containment zone. Examples of suitable mechanisms include physical means, such as mechanical or electronic door interlocks (equipped with manual overrides for emergency exit), visual or audible alarms, or, operational means, such as SOPs and signs preventing personnel from opening doors simultaneously.
3.3.18	Mechanical or electronic door interlocks (equipped with manual overrides for emergency exit) prevent the simultaneous opening of anteroom critical door(s) with adjacent and sequential anteroom doors, which maintains the negative air pressure differentials and limits the migration of potentially contaminated air into the "clean" change area or outside the containment zone.
3.3.19	Preventing the simultaneous opening of chemical decontamination shower doors maintains the negative air pressure differentials and limits the migration of potentially contaminated air into the change areas of the anterooms.

Requirement Number(s)	Explanatory Note
3.3.20	Sealable doors (e.g., three-sided or four-sided gasket, four-sided door jamb) are designed to allow leakage of air under normal operating conditions yet are capable of being sealed to isolate individual animal cubicles and PM rooms for gaseous decontamination and pressure decay testing when needed.
3.3.21	Airtight doors (e.g., inflatable air pressure resistant or compression seals) are designed to ensure 0% leakage of air under normal operating conditions to maintain the integrity of the containment barrier and to withstand pressure decay testing and gaseous decontamination.
3.4.1	Cleanable and resistant surface materials and finishes (e.g., paint, epoxy, and other protective finishes) provide protection against the stresses associated with activities performed inside the containment zone, which may include repeated decontamination (e.g., chemical, gaseous), frequent high pressure washing in animal containment zones, and activities causing impacts and scratches (e.g., movement of large-sized animals across floors, equipment resting on surfaces, animal cages). Other examples of surfaces that may become contaminated as a result of the procedures in use or spills of infectious material or toxins, and require decontamination, include animal holding units, shelves, and interiors of drawers and cabinets, as determined by the activities and function of the containment zone. Non-absorbent materials may include stainless steel, epoxy resin surfaces or chemical resistant plastic laminate for benchtops, and urethane or vinyl for stools and chairs.
3.4.2	The continuity of adjacent surfaces (e.g., walls and floors, benchtops and other work surfaces) and overlapping material (e.g., flooring, baseboards, coving, backsplashes) provides a continuous barrier designed to prevent contaminated liquids from reaching surfaces that are hard to access and decontaminate. Heat welding or a continuous bead of silicone sealant, such as caulking, can be used to create a continuous surface.
3.4.3	Smooth rims and corners reduce the risk of punctures or tears in positive-pressure suits that could result in exposure to pathogens or toxins.

Requirement Number(s)	Explanatory Note
3.4.4	Backsplashes that are continuous or sealed at the junction between the wall and bench provide a continuous barrier designed to prevent contaminated liquids from reaching surfaces that are hard to access and decontaminate. Heat welding or a continuous bead of silicone sealant as caulking can be used to create a continuous surface.
3.4.5	Slip-resistant floors (e.g., textured surfaces) help prevent slips and falls and the associated risk of exposure to infectious material or toxins (e.g., via a splash, spill, inoculation or scratch). Different rooms or spaces may require a different degree of slip resistance (i.e., coefficient of friction), as determined by the activities and function of the different spaces inside the containment zone (e.g., animal room versus a storage room).
3.4.6	Appropriate floor design (including floor joists, spacing, and trusses) and materials allow flooring to resist damage and withstand the anticipated loads represented by heavy animals and caging equipment, as applicable.
3.4.7	The continuity of the seal between the floor and wall allows liquids on the floor to be contained and facilitates decontamination after a spill in a laboratory work area and routine cleaning and decontamination of animal rooms and cubicles. Heat welding or continuous bead of silicone sealant, such as caulking, can be used to create a continuous surface.
3.4.8	The continuity of the seal between the wall and ceiling facilitates maintenance, cleaning, and decontamination. Heat welding or continuous bead of silicone sealant, such as caulking, can be used to create a continuous surface.
3.4.9	Interior surfaces (i.e., walls, floors, ceiling) made of materials that limit the penetration of gases and liquids (e.g., stainless steel, epoxy resin or laminate covering, non-porous materials) provide room integrity, facilitate surface and room decontamination, and serve to contain any large volumes of contaminated liquids that may be present (e.g., animal wastes, large scale process fluids).

Requirement Number(s)	Explanatory Note
3.4.10	Minimizing and appropriately shielding protruding obstructions (e.g., pipes, conduits) prevents injury to animals and personnel. It also helps prevent containment breaches caused by damage to the protruding obstruction by a large-sized or distressed animal.
3.5.1	IDA, established by HVAC system design through negative air pressure differentials, ensures that air flows from areas of lower containment or low risk of contamination to areas of higher containment (i.e., higher risk of contamination), never the reverse. This prevents the release and the spread of contamination to lower levels of containment by establishing a physical containment barrier of air against airborne or aerosolized infectious material or toxins. For example, IDA forces air to flow from the "clean" change area into the "dirty" change area, from the "dirty" change area into the laboratory work area, and from the laboratory work area into the animal cubicle.
3.5.2	IDA, established by HVAC system design through negative air pressure differentials, ensures that air flows from areas of lower containment or low risk of contamination to areas of higher containment (i.e., higher risk of contamination), never the reverse. This prevents the release and the spread of contamination to lower levels of containment by establishing a physical containment barrier of air against airborne or aerosolized infectious material or toxins. For example, IDA forces air to flow from the "clean" change area into the "dirty" change area, from the "dirty" change area into the laboratory work area, and from the laboratory work area into the animal cubicle.
3.5.3	Monitoring devices that visually demonstrate IDA (e.g., magnehelic gauge, floating ball, alarms) allow personnel to verify that the HVAC system is working properly and that IDA is being maintained.
3.5.4	Pressure differential monitoring lines that penetrate the containment barrier designed to prevent the migration of potentially contaminated air (e.g., provided with HEPA filtration, small in-line filters, or fully sealed) protect against the release of aerosolized or airborne infectious material or toxins in the event of positive pressurization due to HVAC system failure.

Requirement Number(s)	Explanatory Note
3.5.5	Alarms that indicate HVAC system failure (e.g., strobic visual alarms, intercom audible alarms) are critical to protect and enable personnel, both inside and outside the containment zone, to quickly initiate emergency procedures and repairs to prevent containment breaches.
3.5.6	Independent supply and exhaust air systems prevent the contamination of areas outside the containment zone in the event of HVAC system failure or airflow reversal. Where air systems in CL3 are combined with those of other areas, HEPA filters or isolation dampers (e.g., gas-tight dampers, bubble-tight dampers) are examples of backdraft protection that can be used to prevent contaminated air from reaching areas of lower containment.
3.5.7	Backdraft prevention on supply air ductwork prevents the contamination of supply air ductwork outside of the containment barrier in the event of HVAC system failure or airflow reversal. HEPA filters or isolation dampers (e.g., gas-tight damper, bubble-tight damper) are examples of backdraft protection that can be used on the supply air duct.
3.5.8	HEPA filters provide backdraft protection and prevent infectious material and toxins from being released in the event of HVAC system failure or airflow reversal.
3.5.9	Air system interlocks shutdown or divert the supply air system automatically (i.e., without relying on user intervention) upon failure of the exhaust air system to prevent sustained air positive pressurization of the containment zone and to prevent the release of infectious material and toxins. Examples of HVAC system interlocks include control logic built into the containment zone's building automation system and hard-wired connections between the supply air and exhaust air fans.
3.5.10	Filtering exhaust air before recirculation or directly venting exhaust air to the outdoors protects against infectious aerosols or aerosolized toxins from being recirculated within the containment zone or building.

Requirement Number(s)	Explanatory Note
3.5.11	Filtering exhaust air protects against airborne infectious material, infectious aerosols, or aerosolized toxins from being recirculated within the containment zone or building. HEPA filtration of the exhaust air adds a higher level of protection to prevent the release of infectious material and toxins from the containment zone.
3.5.12	Filtering exhaust air protects against airborne infectious material, infectious aerosols, or aerosolized toxins from being recirculated within the containment zone or building. HEPA filtration of the exhaust air adds a higher level of protection to prevent the release of infectious material and toxins from the containment zone. Including two stages of HEPA filtration provides backup protection against the release of RG4 pathogens.
3.5.13	Certified HEPA filters are factory manufactured and tested in accordance with the applicable IEST standard to demonstrate that they meet their design function.
3.5.14	HEPA filter housings designed to withstand the pressures associated with regular operation, gaseous decontamination, and the applied pressures associated with routine integrity testing of containment zone ductwork (i.e., pressure decay testing), reduce the potential of rupture or developing a leak through which infectious material and toxins could be released.
3.5.15	A mechanism to isolate HEPA filters (i.e., isolation dampers such as gas tight damper, bubble tight damper) is critical to prevent the release of contaminated air when removing, decontaminating, or testing (e.g., *in situ* scan testing) filters.
3.5.16	An airtight seal on containment zone supply air ductwork prevents the release of infectious material and toxins and facilitates gaseous decontamination.
3.5.17	An airtight seal on containment zone exhaust air ductwork prevents the release of infectious material and toxins and facilitates gaseous decontamination.

Requirement Number(s)	Explanatory Note
3.5.18	Location of airflow control devices is critical for the effective control of HVAC systems. This can be best achieved by locating airflow control devices on the supply air system on ductwork outside the containment barrier, upstream of the supply isolation backdraft damper or HEPA filter; and by locating airflow control devices on exhaust air systems on ductwork outside the containment barrier, downstream of the exhaust HEPA filter.
3.5.19	Sections of the air supply and exhaust systems, including ductwork and fans, outside the containment barrier require regular repairs, maintenance, cleaning, and inspections to confirm that the HVAC system continues to operate as designed. This is best achieved by locating these sections of the air supply and exhaust systems so that they are easily accessible by maintenance and other personnel.
3.6.1	Stand-off fasteners (e.g., surface mounted brackets) prevent the accumulation of contamination (e.g., bedding, contaminated liquids) behind conduits, piping, and other services by allowing accessibility for maintenance, cleaning, and decontamination.
3.6.2	Shut-off valves and other controls for the main water supply are located outside the containment zone to provide better accessibility to maintenance and other personnel for regular maintenance, repair, inspection, and emergency shut-off.
3.6.3	Backflow prevention (e.g., reduced pressure principle systems, dual check valves) and isolation valves (e.g., gate valves) on containment zone water supply piping prevent potentially contaminated water or air from entering water supply piping and allow control of water supply for emergency shut-off.
3.6.4	Handwashing prevents the spread of many types of pathogens and toxins outside of the containment zone. Locating a dedicated sink near the point(s) of exit from the containment zone reduces the risk of recontaminating hands after washing but before exit. Designating a laboratory sink for handwashing is an alternate example to facilitate handwashing by personnel upon exit.

Requirement Number(s)	Explanatory Note
3.6.5	Handwashing sinks with "hands-free" capability (e.g., electronic eyes/infrared sensors, foot pedals/pumps, elbow-controlled taps) reduce contamination of the sink area and the potential for recontaminating washed hands.
3.6.6	Emergency eyewash and shower equipment provide on-the-spot treatment to flush out, dilute, and remove any hazardous materials, including infectious material or toxins, that have contaminated the eyes, face, or body before serious injury can occur.
3.6.7	Design features, such as capped or raised floor drains, are incorporated into large scale production areas to prevent the inadvertent release of infectious material or toxins into sanitary sewers.
3.6.8	Dikes or dams are used in areas where large scale process equipment is kept to contain the full volume of large scale process fluids in the event of a leak or a spill and prevent the release of infectious material and toxins to the sanitary sewer.
3.6.9	Drainage traps create a water seal that prevents contaminated air within the containment zone from entering the piping, sewer, and/or effluent decontamination systems. Deep seal "P"-traps with a seal depth of 125 mm or greater is a common example used in containment zones where negative air pressure differentials are present.
3.6.10	Independent drain lines connected directly to an effluent decontamination system prevent contaminated liquids from entering drain lines that service other areas, or the sanitary sewer system.
3.6.11	The collection and redirection of autoclave condensate to drains servicing areas inside the containment barrier prevent the release of potentially contaminated liquids from the autoclave and directs them to an effluent decontamination system so that they are decontaminated prior to release to the municipal sewage system. Closed connections prevent the release of the condensate before entering the drain; open connections are only acceptable where the drain is located inside the containment barrier or when the autoclave is equipped with an auto-decontamination function that will effectively decontaminate the steam condensate internally.

Requirement Number(s)	Explanatory Note
3.6.12	Plumbing vent lines that are HEPA filtered or independent from those of lower levels of containment prevent the release of infectious material and toxins into the piping that services other areas.
3.6.13	Plumbing vent lines that are HEPA filtered prevent the release of infectious material and toxins into the piping that service other areas. Isolation dampers (i.e., bubble-tight or gas-tight) or other means of properly isolating filters, allow the filters to be isolated for gaseous decontamination.
3.6.14	Plumbing vent lines that are HEPA filtered and independent from those of lower levels of containment provide backup mechanisms to prevent the release of infectious material and toxins from CL4 into the piping that service other areas. Isolation dampers (i.e., bubble-tight or gas-tight) or other means of properly isolating filters, allow the filters to be isolated for gaseous decontamination.
3.6.15	For personnel safety, supplied breathing air and hose connections are provided in all areas of CL4 zones where positive-pressure suits are worn, including chemical showers and suit change rooms.
3.6.16	In the event that the supplied breathing air system fails, backup air supply systems (e.g., backup air cylinders, reserve air tank) need to provide enough air to allow time for emergency evacuation of all personnel from CL4 zones where positive-pressure suits are worn.
3.6.17	Locating light ballasts and starters outside the containment barrier makes them readily accessible to personnel for maintenance and repair.
3.6.18	The continued operation of equipment critical for the containment and security of infectious material and toxins (e.g., BSCs, ventilated cage racks, electronic controlled access systems) during power outages is crucial to maintain containment integrity and to safeguard the security of the zone. In high containment zones, this includes HVAC systems and controls, as well as equipment essential for personnel safety (e.g., air supply). Emergency power can be provided through the building generator or a UPS system.

Requirement Number(s)	Explanatory Note
3.6.19	In situations where a delay may occur before emergency power is supplied, UPS allows the continued operation of life safety equipment (e.g., supplied air to positive-pressure suits), building automation systems, and security systems (e.g., electronic controlled access systems, closed circuit television).
3.7.1	When properly maintained and used in conjunction with good laboratory techniques, primary containment devices provide effective personnel and environmental protection when working with open vessels of infectious material, toxins, or infected animals. Examples of primary containment devices include BSCs, fermenters, primary containment caging (e.g., microisolator cages), ventilated cage racks, and centrifuges with sealable cups or rotors.
3.7.2	When properly maintained and used in conjunction with good laboratory techniques, primary containment devices provide effective personnel and environmental protection when working with open vessels of infectious material, toxins, or infected animals. Examples of primary containment devices include BSCs, fermenters, primary containment caging (e.g., microisolator cages), ventilated cage racks, and centrifuges with sealable cups or rotors.
3.7.3	In the event of an exhaust fan failure, Class II B2 BSCs can produce a reversal of airflow from the face of the BSC (i.e., puff-back) as a result of a delayed reaction to shutdown. Every effort should be made to eliminate puff-backs mechanically (e.g., supply blower brake, isolation damper for BSC supply intake). Where puff-backs cannot be eliminated, it can be physically minimized (i.e., duration and airflow velocity as low as achievable) and additional operational mechanisms can be implemented to address the risks associated with the puff-back, based on the pathogen(s) and procedure(s) in use. Examples of operational mechanisms include the use of additional PPE, such as respirators and face protection, by all personnel in the immediate work area, and posting emergency protocols to be followed in the event puff-back occurs.

Requirement Number(s)	Explanatory Note
3.7.4	Preventing the release of infectious material and toxins from process equipment, closed systems, and other primary containment devices prevents contamination and protects personnel. This may include the use HEPA filters on ports and vents, incineration, gaseous decontamination, or fully enclosing the primary vessels in ventilated housings that are exhausted through HEPA filters (e.g., walk-in containment enclosure).
3.7.5	Sensing devices (e.g., to monitor pressure, temperature) continually monitor the integrity of process equipment and closed systems during large scale processes and production, allowing failures to be immediately signaled to personnel by audible or visual alarms in order to initiate emergency procedures or repairs before a breach of containment occurs.
3.7.6	The protective air curtain created at the front of the BSC is quite fragile and can be easily disrupted by air currents or drafts created by traffic or HVAC systems in close proximity. Locating a BSC away from high traffic areas, doors, open windows, and air supply/exhaust diffusers protects the BSC air curtain and protects personnel from exposure and the release of pathogens and toxins.
3.7.7	The construction and installation of large pieces of equipment used in large scale processes and production in a way that allows for an effective means of cleaning and decontamination (e.g., auto-decontamination or sterilization cycle) reduces the risk of exposure to the infectious material or toxins.
3.7.8	Primary containment caging systems are designed to prevent the release of pathogens, infectious material, or toxins shed by infected animals or animals that have been intentionally exposed to a pathogen or toxin. Ventilated microisolator cages are an example of animal caging that could be used in an SA zone.

Requirement Number(s)	Explanatory Note
3.7.9	Primary containment caging systems with HEPA filtration either on the individual cage (e.g., filter-top cage) or through a ventilated enclosure (e.g., microisolator cages in a HEPA ventilated cage rack) are designed to protect personnel and prevent the release of pathogens, infectious material, or toxins shed by infected animals or animals that have been intentionally exposed to a pathogen or toxin.
3.7.10	Preventing animal escape is fundamental to protecting personnel and animal safety, as well as preventing the release of infectious material or infected animals.
3.7.11	The decontamination of waste and other contaminated material inside the containment zone or their safe and secure transport to a decontamination area (e.g., centralized facility decontamination location or certified off-site waste disposal service) prevent the release of pathogens from the containment zone. Examples of decontamination technologies include autoclaves and incinerators.
3.7.12	Decontamination technologies (e.g., autoclaves, incinerator) within the containment barrier allow for the decontamination of materials prior to their removal from the zone.
3.7.13	Decontamination technologies (e.g., double-door autoclave, dunk tanks, fumigation chamber) provided on the containment barrier allow for the decontamination of all materials prior to removal from the containment zone, and eliminates the possibility of the material becoming recontaminated before leaving the zone.
3.7.14	Monitoring of operational parameters such as date, cycle number, time, temperature, chemical concentration, and pressure confirms that the decontamination technology is working properly (i.e., verifying that parameters are achieving validated levels).
3.7.15	The appropriate temperature and treatment time to effectively decontaminate waste materials are determined based on pathogen(s) in use. For example, an autoclave capable of operating at 134°C is critical for the effective decontamination of all waste materials coming from a containment zone where prions are handled and autoclaving is used as a single-step decontamination process of this material.

Requirement Number(s)	Explanatory Note
3.7.16	Chemical decontamination technologies (e.g., chemical decontamination showers, dunk tanks, effluent decontamination systems) rely on the supply of chemicals for effective decontamination. Maintaining supply tanks of these chemicals at a sufficient level is critical for effective decontamination and to prevent a breach of containment.
3.7.17	Vacuum systems are used to aspirate liquid from a tube or to create a void in filtration units (e.g., centralized vacuum system). Vacuum pumps may cause aerosolization of infectious material or toxins and lead to contamination of vacuum lines and pumps. A device such as a HEPA filter, a small in-line filter (e.g., 0.2 µm filter), or a disinfectant trap can be used to protect vacuum systems from internal contamination with infectious material or toxins.
3.7.18	A communication system increases personnel safety in the event of an emergency in the containment zone, and can also be used to minimize the movement of notebooks/papers and personnel into and out of the containment zone. Examples of communication systems include telephones, fax machines, intercom systems, networked computers, pagers, 2-way radios, and communicating through a window (e.g., notes and signs, hand signals).
3.7.19	Visual monitoring of laboratory work areas, animal zones, and large scale production areas from outside the containment barrier improves personnel safety and allows quick emergency response and assistance.
3.8.1	An effluent decontamination system allows all liquid waste leaving the containment zone to be decontaminated, prior to release into sanitary sewers. Effluent decontamination systems can include holding tank(s) in conjunction with one or more decontamination tanks designed to decontaminate liquid effluent waste by heat or chemical means in a continuous flow or in static volumes (batches).
3.8.2	The appropriate parameters, such as temperature, chemical concentration, and treatment time, to effectively decontaminate pathogens in liquid effluent using a heat-based or chemical-based effluent decontamination system are determined based on the pathogen(s) in use. For example, a temperature-based effluent decontamination system capable of operating at 134°C is critical for the effective single-step thermal decontamination of all liquid waste coming from a containment zone where prions are handled.

Requirement Number(s)	Explanatory Note
3.8.3	Drain piping sloping towards the effluent decontamination system allows for gravity flow and reduces the risk of blockage.
3.8.4	To be effective, it is essential that the entire effluent decontamination system (i.e., piping, joints, valves, and tanks) be able to withstand repeated exposure to the heat and/or the caustic chemicals necessary for decontamination during normal operation. For example, chemical/heat fused or welded joints protect the integrity of the entire system, as confirmed by pressure decay testing.
3.8.5	Rooms housing an effluent decontamination system that serve as a primary decontamination technology are designed to provide the appropriate level of security to prevent unauthorized access, and in the event of an effluent decontamination system failure, to prevent a containment breach by containing any untreated waste.
3.8.6	Rooms housing an effluent decontamination system that serve as a primary decontamination technology are designed to provide the appropriate level of security to prevent unauthorized access, to contain any infectious aerosols or aerosolized toxins, and in the event of an effluent decontamination system failure, to prevent a containment breach by containing any untreated waste.
3.8.7	Sludge and sediments can form blockages inside the effluent decontamination system that are difficult to effectively decontaminate, and impede the proper mechanics of the system. Examples of suitable mechanisms include a grinder, trap, strainer, sloping of the piping, or SOPs for routine maintenance procedures to deal with the sludge and sediment buildup.
3.8.8	Alarm systems (e.g., audible alarm, automated electronic messaging) to indicate failure(s) of the effluent decontamination system allow personnel to quickly respond to a potential issue or emergency situation.
3.8.9	Temperature monitoring devices (e.g., electronic gauges, unit mounted sensors) are essential to verify that the effluent decontamination system reaches and maintains the required temperature for decontamination of the infectious material or toxins. Annual calibration of temperature monitoring devices confirms accuracy and functioning of the devices.

Requirement Number(s)	Explanatory Note
3.8.10	Accurate labelling of all drainage piping leading to an effluent decontamination system allows for the correct identification of these components and a faster response by personnel in the event of a failure or leak. Examples of suitable labelling include colour-coding, directional arrows and hazard symbols.
3.8.11	Readily accessible drainage piping leading to an effluent decontamination system allows maintenance and other personnel access for regular maintenance, repair, and inspection.
3.8.12	HEPA filters provided on plumbing vent lines from the effluent decontamination system prevent the release of pathogens and toxins and the potential downstream contamination of the vent lines.
3.8.13	HEPA filters provided on plumbing vent lines from the effluent decontamination system prevent the release of pathogens and toxins and the potential downstream contamination of the vent lines. Two stages of HEPA filtration provide backup protection against RG4 pathogens.
4.1.1	A robust biosafety program allows for the effective implementation and maintenance of biosafety practices in accordance with the organization's activities and regulatory requirements.
4.1.2	The biosafety representative(s) (i.e., designated BSO in licensed facilities) is responsible for ensuring that the key elements of the biosafety program are implemented to promote the safety and security of the pathogens, toxins, and other regulated infectious material. In order to effectively accomplish these responsibilities, the BSO requires knowledge and experience appropriate for the facility and containment level, and the pathogens and toxins handled.
4.1.3	Keeping contact information current prevents any delays in correspondence, should information need to be relayed to the facility.
4.1.4	Program intent describes the scope of a facility's activities, including the pathogens, toxins, and other regulated infectious material, as well as animal species in use.

Requirement Number(s)	Explanatory Note
4.1.5	Program intent describes the scope of a facility's activities, including the pathogens, toxins, and other regulated infectious material, as well as animal species in use. In containment zones where non-indigenous animal pathogens are handled, submitting changes to program intent or to SOPs that may impact biocontainment or biosafety to the CFIA prior to implementation allows the CFIA to confirm the changes are acceptable and that containment will be maintained.
4.1.6	An overarching risk assessment is a broad assessment that reflects the overall activities being conducted within the facility and is often performed during the initial development or review of a facility's biosafety program.
4.1.7	A biosecurity risk assessment identifies and prioritizes assets, defines threats, and determines risk and mitigation strategies. It is through a biosecurity risk assessment that it is determined whether it is necessary to develop a basic or a complex biosecurity plan.
4.1.8	LRAs are site-specific risk assessments that are conducted to identify hazards based on the infectious material and toxins in use and the activities being performed. They are used to define safe work practices for the activities being performed and to develop SOPs.
4.1.9	A training needs assessment will determine key components of the training program, including objectives, content, target groups, implementation strategy, and retraining cycles.
4.1.10	The Biosafety Manual contains information related to the containment zone. Individual elements of the Biosafety Manual may or may not be housed in a single physical location. For example, in high containment zones, training records may be stored outside the containment zone, while printed copies of SOPs are generally kept inside the containment zone. The Biosafety Manual can be developed using expertise from various individuals such as the BSO, research or technical staff and a medical advisor, if necessary.

Requirement Number(s)	Explanatory Note
4.1.11	A description of the biosecurity plan constitutes one of the elements in the Biosafety Manual. Evaluation and improvement of the biosecurity plan promotes the continued refinement of the overall biosafety program, and may be done following an incident, changes in program intent (e.g., working with a new pathogen), or any other situation that may affect the biosecurity plan (e.g., facility renovations).
4.1.12	A medical surveillance program helps prevent, detect, and treat illnesses associated with the exposure of laboratory personnel to pathogens and toxins. The focus of the program is primarily preventive, although it also provides a response mechanism through which a potential infection or intoxication can be identified and treated in a timely manner.
4.1.13	LRAs and the requirements set out in other provincial/territorial and federal legislation determine when respiratory protection is needed.
4.1.14	The training program includes topics such as the Biosafety Manual, SOPs, entry/exit procedures, emergency response, and PPE. Evaluation and improvement of the training program is critical for accuracy and relevancy and to provide staff with training appropriate to their work.
4.1.15	SOPs are the foundation for safe work practices and describe the specific chain of events for a particular activity.
4.1.16	A comprehensive ERP allows personnel to react quickly and appropriately in a predetermined manner to emergency situations. It sets out the procedures that personnel need to follow in response to various emergency situations, in order to protect their health and safety, to prevent the release of pathogens and toxins from the containment zone, as well as to protect the security of the biological material stored within the zone.

Requirement Number(s)	Explanatory Note
4.2.1	Due to the increased risks associated with RG4 pathogens, establishing a liaison with the local hospital or health care facility allows medical staff to be aware of the pathogens that are handled or stored in the containment zone, so that they can establish appropriate procedures for treatment in the event of an accidental exposure.
4.2.2	Informing the appropriate internal personnel or authority promptly of any potential exposure incidents or disease that is potentially related to an exposure in the containment zone allows for rapid initiation of the facility's internal investigation process to determine if an exposure (i.e., inhalation, ingestion, inoculation, or absorption of a pathogen or toxin) has occurred. This will allow for timely follow up actions to be taken to reduce or mitigate any further impacts including prompt: identification and implementation of corrective actions to prevent other potential exposures or further spread; administration of the appropriate post-exposure and medical treatment; and notification of the PHAC of the exposure incident.
4.2.3	Due to the high virulence of RG4 pathogens, immediate investigation of unexpected work absences of CL4 personnel allows for prompt medical attention to be obtained should the absence be related to a possible exposure incident.
4.2.4	An emergency medical contact card provided by the employer summarizes important information regarding higher risk pathogens or toxins, as determined by an LRA, or the risk of exposure to Macacine herpesvirus 1 (which is carried by certain non-human primates, such as macaques), where non-human primates are being handled. This card can provide information on pathogens that cause diseases that are unlikely to be recognized by health care staff, information on routes of transmission, symptoms, and preventive and therapeutic treatments.

Requirement Number(s)	Explanatory Note
4.2.5	An emergency medical contact card provided by the employer summarizes important information regarding the RG4 pathogens, and any other infectious material handled, as determined by an LRA, or the risk of exposure to Macacine herpesvirus 1 (which is carried by certain non-human primates, such as macaques), where non-human primates are being handled. This card can provide information on pathogens that cause diseases that are unlikely to be recognized by health care staff, information on routes of transmission, symptoms, and preventive and therapeutic treatments.
4.3.1	The Biosafety Manual contains information essential for promoting a safe and secure workplace. Training on its relevant aspects, including associated SOPs, is critical in the understanding of its contents by trainees and personnel.
4.3.2	Training personnel on the potential hazards and mitigation strategies associated with the infectious material or toxins in use helps prevent exposures and the release of contaminated materials. Providing training on general signs and symptoms of concern helps staff quickly identify potential exposure incidents.
4.3.3	In order to reduce the risk of personnel exposure and to maintain containment of infectious material and toxins, personnel need to understand the operation and design of containment zone systems relevant to their activities. This may include the detection of system failures and determining when it is safe, or not, to enter the containment zone.
4.3.4	Training on the safe use of laboratory equipment, including BSCs and other primary containment devices, increases the likelihood that the devices will be utilized correctly and increases personnel safety from exposures.
4.3.5	Since animals can behave unpredictably, and different species have different risks, providing training in animal restraint and handling techniques increases both personnel and animal safety, especially when the animal is diseased or has been exposed to a pathogen or toxin.

Requirement Number(s)	Explanatory Note
4.3.6	Accompanying and training individuals requiring temporary access to the containment zone confirms and encourages the correct use of procedures. This helps protect the individuals against exposure and helps prevent breaches of containment.
4.3.7	Having personnel that are knowledgeable of the SOPs used in the containment zone and proficient in their use reduces the potential for exposure or release when infectious material or toxins are being handled.
4.3.8	To protect all personnel from exposure and to help prevent breaches of containment, the direct supervision of trainees by a trained individual confirms that correct procedures are followed when handling infectious material and toxins or when responding to an incident or accident.
4.3.9	Trained and knowledgeable staff creates a safer and more secure work environment and help prevent breaches of containment. Reviewing the training needs assessment on an annual basis will identify gaps in the current training program. These gaps can be addressed by additional or refresher training.
4.3.10	Annual refresher training on emergency response procedures confirms that personnel remain knowledgeable on these infrequently used procedures and that they can respond immediately and effectively to emergencies.
4.4.1	Using, wearing and storing dedicated PPE, such as lab coats, aprons, solid-front gowns, coveralls, full body suits, and disposable sleeves, in a specified area (e.g., CL3 laboratory, CL2 animal cubicle, or CL3 PM room) protects individuals from exposure and prevents the spread of contamination outside of the containment zone.
4.4.2	Wearing eye or face protection (e.g., goggles or face shield) protects personnel from exposure by preventing infectious material and toxins from coming into contact with the mucous membranes of the eyes, and where full face protection is worn, the nose, or mouth.

Requirement Number(s)	Explanatory Note
4.4.3	Wearing dedicated footwear (e.g., boots or shoes) or additional protective footwear (e.g., boot or shoe covers) at all times in animal rooms, animal cubicles, and PM rooms protects individuals from exposure by preventing the spread of contamination outside of the containment zone.
4.4.4	Wearing appropriate gloves (e.g., latex, nitrile, vinyl) protects personnel from exposure and prevents the spread of contamination by protecting hands from contamination.
4.4.5	Full body coverage dedicated protective clothing (e.g., protective suits, coveralls, surgical scrubs in conjunction with lab coat or back closing gown) protects personnel from exposure by providing a layer of protection between personnel and the infectious material and toxins.
4.4.6	Dedicated protective clothing and shoes (e.g., full body suits, coveralls, surgical scrubs in combination with dedicated lab coat or back closing gown), that are worn only inside the containment barrier (i.e., completely removed upon exit), prevent the spread of contamination and protect against the release of infectious material or toxins from the containment zone.
4.4.7	An additional layer of protective clothing (e.g., solid-front gowns with tight-fitting wrists, waterproof aprons, head covers) protects personnel from exposure by providing an additional layer of protection in the event that the outer layer of protective clothing is compromised or contaminated.
4.4.8	In CL4 zones where work is not performed entirely in a Class III BSC line, positive-pressure suits that function properly (as determined by integrity testing) protect personnel from exposure by providing an additional layer of protection between personnel and the infectious material and toxins, as well as delivering clean, breathable air.
4.4.9	Respirators protect personnel from airborne pathogens, infectious aerosols, or aerosolized toxins that are not contained in a primary containment device (e.g., a certified BSC or HEPA-filtered cage).

Requirement Number(s)	Explanatory Note
4.5.1	Doors are kept closed to maintain the integrity of the containment barrier, to maintain security, and to prevent animal escape. In high containment zones, keeping doors closed is also essential for the proper operation of the HVAC system.
4.5.2	Limiting access to the containment zone, animal rooms, animal cubicles, and PM rooms to authorized personnel protects the safety of individuals entering the containment zone and the security of all biological material in the zone.
4.5.3	Due to the increased biosecurity risks associated with SSBAs, only individuals having a valid HPTA security clearance issued by the PHAC are allowed to enter the part of a the facility where SSBAs are handled and stored. A HPTA security clearance is not necessary when an individual is accompanied and supervised, or when the SSBAs are not present or are locked up and inaccessible.
4.5.4	Due to the increased biosecurity risk associated with SSBAs and to limit the number of personnel able to access the SSBA, only individuals requiring access to the part of the facility where SSBAs are handled and stored are allowed in that area.
4.5.5	Limiting access to mechanical and electrical services supporting the containment zone (e.g., electrical panels, mechanical penthouse, and HVAC system control areas) to authorized personnel protects the safety of individuals entering these areas and the security of all biological material in these areas and the containment zone.
4.5.6	Limiting access to mechanical and electrical services supporting the containment zone (e.g., water supply shut-off valves and controls, mechanical penthouse, electrical panels, and HVAC system control areas) to authorized personnel protects the safety of individuals entering these areas and the security of all biological material in these areas and the containment zone.
4.5.7	Limiting access to rooms housing an effluent decontamination system to authorized personnel protects the safety of individuals entering these areas and protects against the release of pathogens and toxins.

Requirement Number(s)	Explanatory Note
4.5.8	Posting entry requirements at the point(s) of entry keeps individuals entering the containment zone, animal room, animal cubicle, or PM room informed of special entry requirements (e.g., PPE or additional safety requirements that may exist depending on the nature of the activities being conducted).
4.5.9	Verification of the correct readings on the airflow monitoring devices allows personnel to confirm that proper airflow is provided before they enter the area.
4.5.10	Storing personal clothing separate from dedicated PPE (including protective clothing, where worn), either outside the containment barrier or in dedicated change areas, protects individuals from exposure by preventing cross-contamination to personal clothing and the spread of contamination outside of the containment barrier.
4.5.11	Keeping personal belongings (e.g., outerwear, backpacks, purses, cell phones, mp3 players) out of areas where infectious material or toxins are handled or stored protects individuals from exposure by preventing the contamination of these items and the spread of contamination outside of the containment barrier. This also avoids the need to subject personal belongings to the destructive effects of the decontamination process in the event it becomes contaminated.
4.5.12	Leaving personal belongings (e.g., cell phones, mp3 players, purses, outerwear) outside the containment zone or in assigned change areas outside the containment barrier protects individuals from exposure by preventing the contamination of these items and the spread of contamination outside of the containment barrier. This also avoids the need to subject personal belongings to the destructive effects of the decontamination process upon exit from the containment barrier.
4.5.13	Removing personal clothes/footwear and donning of dedicated protective clothing, including dedicated protective footwear, protects individuals from exposure by preventing the contamination of personal clothing and footwear and the spread of contamination outside of the containment barrier.

Requirement Number(s)	Explanatory Note
4.5.14	Removing dedicated PPE in a particular order (i.e., gloves last) or manner that protects personnel from exposure by preventing the contamination of skin and hair and by reducing the potential of creating aerosols.
4.5.15	Gloves are the last piece of PPE that is removed when exiting a containment zone. Handwashing is performed after removing gloves, immediately before leaving the containment zone so that hands are not recontaminated before exit. Handwashing is one of the most effective ways to protect personnel from potential exposure by preventing the spread of many types of pathogens and toxins through the inadvertent contamination of surfaces, objects, or other items that may be touched outside of the containment zone.
4.5.16	Gloves are the last piece of PPE that is removed when exiting a containment zone. Handwashing is performed after removing gloves, at the containment barrier immediately before leaving the containment zone, animal cubicle or PM room, so that hands are not recontaminated before exit. Handwashing is one of the most effective ways to protect personnel from potential exposure by preventing the spread of many types of pathogens and toxins through the inadvertent contamination of surfaces, objects, or other items that may be touched outside of the containment zone.
4.5.17	Removing dedicated PPE or the additional layer of PPE (e.g., dedicated scrubs, boots, coveralls, lab coats, aprons, gowns, full body suits, shoe covers, head and face protection), when exiting the containment barrier of animal cubicles, PM rooms, or the containment zone protects individuals from exposure by preventing the spread of contamination outside of the containment barrier.
4.5.18	Eyeglasses can become contaminated when worn inside the containment zone. Decontamination of eyeglasses at the containment barrier protects individuals from exposure by preventing the spread of contamination outside of the containment barrier.

Requirement Number(s)	Explanatory Note
4.5.19	Removing all clothing worn inside the containment barrier, including undergarments, and showering out upon exit of the animal cubicle, PM room, or containment zone prevents the spread of contamination outside of the containment barrier and protects the community by preventing the release of non-indigenous animal pathogens.
4.5.20	Removing all clothing worn inside the containment barrier, including undergarments, and showering out upon exit of the animal cubicle, PM room, or containment zone prevents the spread of contamination outside of the containment barrier and protects the community by preventing the release of pathogens and toxins.
4.5.21	Exit procedures from CL4 zones are particularly stringent given the nature of RG4 pathogens. A chemical shower to remove potential contamination from positive-pressure suits, followed by the removal of all clothing worn inside the containment barrier, including undergarments, and showering protects individuals from exposure and prevents the spread of contamination outside of the containment barrier.
4.6.1	Prohibiting activities such as eating, drinking, applying cosmetics, inserting ear buds, or inserting/removing contact lenses reduces the risk of personnel exposure through the contact of mucous membranes of the eyes, nose, ears and mouth with contaminated or potentially contaminated items.
4.6.2	Restraining or covering hair (including beards) reduces the risk that it becomes contaminated through accidental contact with gloved hands, specimens, containers, equipment, or surfaces.
4.6.3	Completely enclosed footwear prevents exposure, contamination, or injury to the feet. Non-slip footwear, with low or no heels, prevents slipping or tripping and enhances personnel safety.

Requirement Number(s)	Explanatory Note
4.6.4	Jewellery may become contaminated or impede personnel decontamination (e.g., via handwashing, showering) if infectious material and toxins become trapped between these items and the skin. Jewellery may also interfere with PPE (e.g., tear gloves or positive-pressure suits). This also avoids the need to subject jewellery to the destructive effects of the decontamination process upon exit.
4.6.5	Oral pipetting, or mouth aspiration, of any substance, especially infectious material or toxins is strictly prohibited in the containment zone to prevent the ingestion or aspiration of infectious material or toxins.
4.6.6	Intact skin provides protection from infection and intoxication. Any breach of the skin (e.g., scratch, cut, wound, rash) may provide a portal of entry for pathogens and toxins, and needs to be protected with a bandage or other suitable waterproof dressing.
4.6.7	Maintaining traffic flow patterns for the movement of personnel, equipment, samples, and animals from areas of least contamination (i.e., clean) to areas of greatest contamination (i.e., dirty) limits the spread of contamination.
4.6.8	Separating spaces dedicated to report writing and other paperwork from areas where infectious material or toxins are actively handled protects against contamination of these areas and any associated materials and supplies that cannot be easily decontaminated.
4.6.9	Needles, syringes, and other sharp objects can cause punctures or needlestick injuries, and potentially result in the injection or inoculation of personnel. Examples of suitable alternatives include safety-engineered needles and plasticware.
4.6.10	Needles, syringes, and other sharp objects can cause punctures or needlestick injuries, and potentially result in the injection or inoculation of personnel. There is a high risk of exposure from a needlestick injury when performing activities such as bending, shearing, re-capping, or removing needles from syringes that contain pathogens or toxins.

Requirement Number(s)	Explanatory Note
4.6.11	The regular decontamination of work surfaces with an appropriate disinfectant or neutralizing chemical minimizes the spread of contamination and protects personnel from inadvertent exposure to pathogens and toxins.
4.6.12	Having access to appropriate emergency assistance during and after regular work hours enhances the personal safety of containment zone personnel in the event of an emergency situation.
4.6.13	Routine verification that IDA is being maintained is essential to identify potential breaches of the containment barrier.
4.6.14	The integrity of primary containment devices is verified to confirm that they are functioning as intended and to prevent personnel exposure to pathogens or toxins resulting from a breach of containment.
4.6.15	Moving or repairing BSCs can damage seals or the HEPA filter, and result in a breach of containment. Certifying BSCs in accordance with applicable standards or specifications (e.g., NSF/ANSI 49 or manufacturer's specifications, as applicable) confirms the integrity of the HEPA filter and seals, and that the BSC is functioning as specified to prevent exposure of individuals and the release of infectious material and toxins into the environment.
4.6.16	Daily verification of containment and life safety system such as IDA, supply air, disinfectant level in the chemical shower, and effluent decontamination systems, are critical to maintain containment and to protect personnel working in the containment zone.
4.6.17	The integrity of positive-pressure suits is verified to confirm that they are functioning as intended to prevent personnel exposure and deliver clean, breathable air.
4.6.18	Good microbiological laboratory practices (i.e., including the use of PPE, handwashing, disinfecting work areas, use of procedures that minimize the creation of aerosols, and proper decontamination and disposal of materials) protect containment zone personnel from exposure by reducing the risk of cross-contamination and the spread of contamination.

Requirement Number(s)	Explanatory Note
4.6.19	Handling pathogens, toxins, and other regulated infectious material in containment zones that do not meet the minimum requirements can result in personnel exposure incidents or the accidental release of the pathogens and toxins.
4.6.20	Safe and secure storage of pathogens, toxins, and other regulated infectious material is critical to prevent the release of infectious material and toxins. Additional precautions are necessary for proper identification and security of all pathogens, toxins, and other regulated infectious material stored outside the containment zone.
4.6.21	Safe and secure storage of pathogens, toxins, and other regulated infectious material is critical to prevent the release of infectious material and toxins. Additional precautions are necessary for proper identification and security of all infectious material and toxins stored outside the containment zone. For higher risk pathogens and toxins, this includes the additional precaution of storage in locked storage equipment that is within an area with limited access.
4.6.22	Safe and secure storage of pathogens, toxins and other regulated infectious material is critical to prevent the release of pathogens and toxins. Additional precautions are necessary for proper identification and security of all pathogens, toxins, and regulated infectious material stored outside the containment zone. Given their dual-use potential, SSBAs have more stringent requirements to safeguard their security. Fridges, freezers, or cabinets that are fixed in place by bolting to the wall or floor so that they are not-movable, and that are locked with a padlock, combination lock, or other means to restrict access, are examples of safe and secure storage equipment for use with SSBAs.
4.6.23	Due to the inherent characteristics of RG4 pathogens (e.g., high virulence and severity of associated diseases, ease of transmission, available host range, impact of introduction or release) and the associated higher level of risk, the security requirements for RG4 pathogens are more stringent, and cannot be stored outside the CL4 containment zone.

Requirement Number(s)	Explanatory Note
4.6.24	BSCs provide effective primary containment while simultaneously providing personnel and environmental protection from infectious aerosols or aerosolized toxins.
4.6.25	BSCs provide effective primary containment while simultaneously providing personnel and environmental protection from infectious aerosols or aerosolized toxins. Given their higher risk, a BSC is used for all activities involving open vessels of RG3 and RG4 pathogens or toxins.
4.6.26	Removing gloves before exiting the BSC is an example of a procedure that protects personnel from exposure and prevents the spread of contamination by preventing the inadvertent contamination of surfaces, objects or other items that may be touched after exiting the BSC. In containment zones where two pairs of gloves are worn when handling infectious material or toxins, the outer pair is removed upon exit from the BSC to avoid the spread of contamination.
4.6.27	Handwashing is one of the most effective ways to prevent the spread of contamination by many types of pathogens and toxins and protects personnel from potential exposure (e.g., from touching eyes or mouth) by preventing the inadvertent contamination of surfaces, objects, or other items that may be touched; this includes activities such as paperwork or computer work, that does not directly involve the manipulation of infectious material. In containment zones where two pairs of gloves are worn when handling infectious material or toxins, the outer pair is removed upon exit from the BSC, and hands are washed immediately after the inner pair is removed.
4.6.28	Centrifugation can create aerosols. When centrifuging infectious material or toxins where inhalation is the primary route of infection or intoxication, sealed safety cups or rotors will contain any infectious aerosols produced. Sealed safety cups and rotors are unloaded in a BSC to protect individuals from exposure to any aerosolized material and prevent the spread of contamination.

Requirement Number(s)	Explanatory Note
4.6.29	Sealed safety cups (or rotors) for centrifugation prevents the release of infectious aerosols and aerosolized toxins. The sealed safety cups (or rotors) are unloaded in a BSC to protect individuals from exposure to any aerosolized material and prevent the spread of contamination.
4.6.30	Open flames (e.g., Bunsen burner) and on-demand open flames (e.g., touch-plate microburner) can damage the BSC HEPA filter and can create turbulence that disrupts airflow patterns. Examples of suitable non-flame alternatives include microincinerators or sterile disposable inoculation loops.
4.6.31	Ensuring that procedures are in place to prevent leaks, spills or drops, or to contain the infectious material and toxins when these events occur, protects personnel from exposure incidents and prevent the accidental release of pathogens and toxins.
4.6.32	Closed systems or other primary containment devices (e.g., fermenters, processing vessels) for use with the large volumes associated with large scale cultures provide effective primary containment and provide personnel and environmental protection from infectious aerosols and aerosolized toxins.
4.6.33	The release of infectious aerosols or aerosolized toxins and the contamination of exposed surfaces can be prevented when collecting samples, adding materials, and transferring culture fluids containing infectious material or toxins from one closed system to another by working through appropriate sampling ports.
4.6.34	Since autologous cells (i.e., cells derived from an individual's own body) are not recognized as foreign by the immune system, the experimental infection of one's own cells may place the individual at a greater risk of infection in the event of an exposure.
4.6.35	A clean, uncluttered work environment allows appropriate decontamination of the containment zone. It also minimizes slipping, tripping, fall, and collision hazards that could potentially lead to exposure incidents or the spread of contamination. Storing excess materials outside the containment zone also protects this material from becoming contaminated.

Requirement Number(s)	Explanatory Note
4.6.36	Routine cleaning by trained cleaning staff reduces contamination. Due to the increased security measures, access controls, and risks associated with the pathogens and toxins in use, these tasks can be assigned to containment zone personnel. Alternatively, where dedicated janitorial staff is expected to perform these activities, authorization to access the containment zone for individual janitorial personnel is provided only upon the completion of all necessary biosafety training and issue of any HPTA security clearances, as applicable.
4.6.37	Preventing the entry/exit of rodents and insects is important to prevent the inadvertent transfer and transport of pathogens and toxins out of the containment zone. Examples of suitable measures include the installation of traps, screens, or door sweeps, in conjunction with regular monitoring and maintenance.
4.6.38	Water seals in drainage traps located in sinks, showers, and floor drains are maintained through regular use or routine filling to prevent the passage of potentially contaminated air and to limit the amount of stagnant contaminated water.
4.6.39	Decontamination of HEPA filters through *in situ* fumigation with formaldehyde or vaporized hydrogen peroxide allows for the decontamination of HEPA filters prior to their removal. In containment zones where prions are handled, an alternative mechanism for the safe removal of HEPA filters is required since prions are not completely inactivated when using the most common decontamination methods. Examples of suitable alternatives include using HEPA filters with a bag-in/bag-out capability or using procedures to contain the HEPA filter for removal followed by its subsequent decontamination.
4.6.40	To avoid interruptions in operation, the availability of a basic tool kit inside high containment zones allows containment zone personnel or trained maintenance personnel to conduct minor repairs that do not require the assistance of a specialized tradesperson. This also avoids the need to subject the tools to the destructive effects of the decontamination process.

Requirement Number(s)	Explanatory Note
4.7.1	Since animals can behave unpredictably, and different species entail different risks, using proper animal restraint and handling techniques provides both personnel and animal safety, especially when the animal is diseased or has been exposed to a pathogen or toxin.
4.7.2	Labelling of primary containment caging housing infected animals is critical for personnel to be aware of the risks associated with the animals.
4.7.3	Animal handling procedures that minimize the creation of aerosols, the dissemination of dust containing infectious material or toxins, and limit the amount of allergens dispersed reduce the risk of personnel exposure and prevent the spread of contamination.
4.7.4	When animal procedures that may lead to aerosolized or airborne pathogens are performed (e.g., necropsy, surgery, inoculation), appropriate procedures for entry to and exit from the animal cubicle or PM room protect individuals from exposure and prevents the spread of contamination. Examples include procedures to avoid the simultaneous opening of doors in a sequence (e.g., anteroom doors) when entering into an animal cubicle or PM room or allowing sufficient time for any aerosols to settle before opening the door to enter/exit.
4.7.5	Live animals are securely moved into and around the containment zone to prevent animal escape and injury. Safe and secure movement of carcasses protects individuals from exposure by preventing the spread of contamination.
4.7.6	Transporting animal carcasses in sealed, leakproof and impact-resistant containers protects individuals from exposure by preventing the spread of contamination. This is not required when transporting via the dirty corridor, as the dirty corridor is considered contaminated.
4.7.7	Inoculation, surgical, and necropsy techniques generally require the use of sharp objects and often have the potential for creating aerosols. The appropriate choice of equipment and the use of skilful techniques prevent punctures or needlestick injuries that could potentially result in the injection or inoculation of personnel.

Requirement Number(s)	Explanatory Note
4.7.8	Conducting inoculation, surgical, and necropsy procedures on small-sized animals in a certified BSC or other appropriate biocontainment device, such as a ventilated animal surgery, downdraft, or backdraft station, provides effective primary containment and protects personnel and the environment from infectious aerosols or aerosolized toxins.
4.7.9	Decontamination and cleaning the skin and hair or feathers of the animal following a procedure protect individuals from exposure and prevents the spread of contamination.
4.8.1	Removing and separately treating gross contamination, especially organic material, is essential to allow the effective decontamination of surfaces and equipment.
4.8.2	Several factors influence the effectiveness of a disinfectant, including the type of pathogen being decontaminated (e.g., virus, bacteria, prion), its state (e.g., vegetative or spore form), as well as the organic load (i.e., the amount of organic material such as soil, bedding, litter, feed, or manure present on a surface or in a suspension) of the material being decontaminated. Neutralizing chemicals for microbial toxins are selected based on the specific physical properties of the particular toxin(s) in use, as there is a wide variety of microbial toxins with considerably different characteristics. Disinfectants and neutralizing chemicals available inside the containment zone allow for decontamination of surfaces (e.g., benchtops and containers) and for quick response to biological spills.
4.8.3	Containers that are leakproof, puncture resistant, and fitted with lids prevent punctures from sharp objects and exposure incidents for containment zone personnel, as well as for individuals handling waste.
4.8.4	Decontamination of BSCs and primary containment devices prior to maintenance protects individuals from exposure when working to maintain these devices. It also prevents the release of pathogens and toxins.

Requirement Number(s)	Explanatory Note
4.8.5	A known or suspected exposure (e.g., from a splash or spill) may lead to the contamination of PPE and clothing. The decontamination of these items following such events protects individuals from exposure and prevents the spread and release of pathogens and toxins.
4.8.6	PPE, including protective clothing, may become contaminated during use. Decontamination of PPE prior to disposal or laundering not only protects personnel from exposure by preventing the inadvertent release of pathogens or toxins, but also protects individuals handling the PPE (e.g., laundry service personnel) once it is removed from the containment zone.
4.8.7	Decontamination of contaminated liquids using a validated method prior to discharge into sanitary sewers prevents the release of pathogens or toxins.
4.8.8	Decontamination of contaminated material, including waste and equipment, or the surface decontamination of transport containers, protects against the inadvertent release of pathogens and toxins from the containment zone, and protects the safety of individuals who handle, clean, and dispose of these materials.
4.8.9	Decontamination of equipment, materials, waste, and the surface decontamination of transport containers at the containment barrier, prior to their removal from the containment zone, prevents the inadvertent release of pathogens and toxins from high containment zones and protects the safety of individuals who handle these materials. Properly labelling the items as decontaminated prevents non-decontaminated items from being inadvertently removed from the containment zone.
4.8.10	Validation of decontamination equipment and processes, when changes in the process are made (e.g., new protocol, parameters, or concentrations) or when new pathogens that have not previously been handled by containment zone personnel, confirms that the equipment is functioning properly and that the process is effective for the decontamination of materials prior to their removal or release from the containment zone.

Requirement Number(s)	Explanatory Note
4.8.11	Verification of decontamination equipment (through the use of biological indicators, chemical integrators, or parametric monitoring devices) is performed upon initial use, and routinely thereafter to confirm that the process is effective for the decontamination of materials prior to their removal from the containment zone. An LRA will help determine the procedures for routine monitoring, taking into consideration the frequency of use of the equipment.
4.8.12	The simultaneous opening of both doors of a double-door barrier autoclave or other pass-through technology will interfere with IDA and may result in a breach of containment. Keeping at least one door closed safeguards containment integrity and prevents the release of pathogens and toxins.
4.8.13	Bedding from infected animals may be contaminated with infectious material and toxins. The use of containment devices (e.g., BSC or a ventilated cage changing station) when handling contaminated bedding protects individuals from exposure and prevents the spread and release of pathogens and toxins. Decontaminating the bedding while still inside the containment cage can achieve the same goal.
4.8.14	Decontaminating animal cubicles, PM rooms, and the dirty corridor whenever they are grossly contaminated and at the end of each experiment protects personnel from exposure by preventing the spread of pathogens and toxins.
4.8.15	A full room decontamination process is validated to confirm it is effective against the pathogens and toxins handled. Full room decontamination may be performed following a spill, at the end of a project, or to facilitate regular preventive maintenance and performance testing.
4.9.1	A comprehensive ERP allows personnel to react quickly and appropriately and in a predetermined manner to emergency situations. It sets out the procedures for personnel to follow in response to various emergency situations, in order to protect them from exposure, and to prevent the release of pathogens and toxins from the containment zone.

Requirement Number(s)	Explanatory Note
4.9.2	Including response procedures for emergencies involving infectious material and toxins that are stored outside the containment zone allows for the continued safe and secure storage of infectious material and toxins, and also prevents the release of pathogens and toxins.
4.9.3	Including response procedures to describe emergency situations in a CL4 zone that could potentially lead to a breach of containment, or loss of breathing air, protects individuals from exposure to pathogens and hazardous chemical decontaminants. Including response procedures in the event of the loss of chemical decontamination shower protects against the spread of contamination and the release of pathogens from the containment zone.
4.9.4	Including response procedures that describe emergency situations where showers are necessary upon exit, protects against the spread of contamination and the release of pathogens and toxins from the containment zone.
4.9.5	Including response procedures for emergency exit to describe situations where normal exit procedures (e.g., showers taken upon exit from the containment barrier) are not followed during life-threatening emergencies, protects against the spread of contamination and the release of pathogens and toxins from the containment zone.
4.9.6	An incident (e.g., a splash or spill) may lead to the contamination of floors and other surfaces. Decontamination following such events protects individuals from exposure and prevents the spread and release of pathogens and toxins. Having a biological spill kit inside the containment zone, and readily available, is essential for a quick spill response and to limit the spread of contamination.
4.9.7	Immediately reporting incidents to the appropriate internal authority as established by the facility's reporting chain allows for a rapid and appropriate response to minimize the risk to personnel (e.g., administration of medical assistance or first-aid), to contain any possible release of pathogens, toxins, and other regulated infectious material, to initiate any repairs or corrective actions to containment systems, and, when applicable, to initiate external notification to the regulatory agencies.

Requirement Number(s)	Explanatory Note
4.9.8	An incident investigation determines the root cause(s) of the incident (i.e., why it took place) and whether it was an isolated event, and may allow new procedures to be implemented to prevent the recurrence of similar events.
4.9.9	The submission of an exposure notification report without delay (i.e., as soon as reasonably possible) allows the PHAC to assess the severity of the exposure incident and assist the licence holder in their response, if requested or necessary. It also prevents other potential exposures.
4.9.10	An exposure follow-up report updates the PHAC on the notified exposure incident and allows for the identification, monitoring, and analysis of trends related to exposures over time. New information is included in the exposure follow-up report and may include the status of the investigation, root cause analysis, risk mitigation strategies put in place to prevent recurrence, and outcomes (if known).
4.10.1	Training records provide information on personnel's participation in training, and their successful completion of training requirements confirms that employees have met all of the training requirements of their position.
4.10.2	An inventory is a list (or lists) of (biological) assets in the possession of the containment zone. Inventories are basic records that allow individuals who are accountable for the control of pathogens, toxins, and other regulated infectious material in a containment zone/facility to manage and control the material. By means of an inventory, a facility manager, containment zone director, or BSO can document and identify the hazards, describe the level of risk in a form readily accessible to personnel, and protect the assets from being misused, misplaced, stolen, abandoned, or released. Inventory information may be accessed in response to an emergency situation where samples need to be relocated (e.g., power outage) or in response to requests from the PHAC or the CFIA (e.g., targeted request for specific pathogens, such as poliovirus stocks). Inventories can exist in many different forms. The specific format (e.g., electronic or paper inventory, a list, a logbook of samples) for establishing and maintaining inventories is determined on an institutional/facility/containment zone level.

Requirement Number(s)	Explanatory Note
4.10.3	An increased level of detail in the inventory is specified due to the increased risk of deliberate theft associated with RG3 and RG4 pathogens and SSBA toxins so that containment zone personnel can quickly determine if any material is missing. In addition to the exact location (e.g., room, freezer, rack, box), inventories containing sufficient detail to identify the specific pathogen or toxin, its risk group, the number of vials and quantity contained in the vials, allow personnel to be aware of the pathogens, toxins, and other regulated infectious material that are stored long-term in the containment zone.
4.10.4	As-built drawings provide a record of all changes made to the specifications and working drawings during the construction process, and show the exact dimensions and location of all elements of the completed facility. In conjunction with physical specifications, and performance and verification test reports, they are a record that demonstrates that the containment zone has been built to meet the physical requirements.
4.10.5	Records, which may include formal internal inspection reports and follow-up notes from a Biosafety Committee or a Health and Safety Committee, or informal notes/documentation on repairs required, are evidence that internal inspections and follow-up actions have been performed.
4.10.6	Records, which can include documentation of BSC testing and reports of certification in accordance with applicable standards and specifications, HEPA filter testing, equipment integrity testing, and building maintenance, are evidence that internal inspections, repair, or testing have been performed.
4.10.7	Calibration certificates are evidence that the instruments used for performance and verification testing were accurate at the time of their use. Calibration certificates from third-party certifiers can be obtained by request, where applicable.
4.10.8	Maintaining records of entry/exit of all individuals (including emergency responders) confirms who was present in the containment zone in the event of an emergency, for biosecurity purposes, and for historical purposes in the event of known or suspected cases of exposure.

Requirement Number(s)	Explanatory Note
4.10.9	Records of validation and routine testing of decontamination technologies and processes provide evidence that the decontamination methods are effective against the infectious material and toxins handled or stored in the containment zone. Records of validation and verification from third-party biohazardous waste disposal facilities can be obtained by request, where applicable.
4.10.10	Maintaining records pertaining to licence activities and animal pathogen import permit requirements for a minimum amount of time allows for the documentation of pathogens, toxins, and other regulated infectious material being, or that have been, handled or stored within the containment zone. It also allows for their review by the PHAC or the CFIA, if requested.
4.10.11	Records of incidents involving pathogens, toxins, other regulated infectious material, or losses of containment allow for the monitoring of trends and can serve to improve systems or procedures. Keeping them on file for the specified periods allows for their review by the PHAC or the CFIA, if required. Lessons learned and corrective actions implemented in response to these reports are a useful reference in future investigations and can also serve as learning tools.
4.10.12	Limiting access to sensitive information, including inventories, pathogen and toxin storage locations, lists of authorized personnel, access codes, and passwords, safeguards the security of the information and of the pathogens and toxins.
5.1.1	Conducting regular performance and verification tests provides proof that the containment systems are functioning as designed and intended and that the minimal acceptable criteria continue to be met. Reports of each test provide a record that demonstrates the appropriate test(s) have been performed. Testing frequency is based on the risks associated with equipment malfunctioning or failing, and is higher for higher containment levels. Tests are performed following any changes, repairs, or modifications to any component that may affect the containment system to confirm it continues to function as intended before operation involving pathogens and toxins resumes.

Requirement Number(s)	Explanatory Note
5.1.2	Faults or deterioration that may affect containment, including faulty equipment, cracked or chipped paint or floors, and faulty lighting, may not be noticed by personnel on a day-to-day basis. Faults and deterioration are identified through routine visual inspections of the containment zone, including surfaces, floors, walls, ceilings, and equipment.
5.1.3	Routine inspection and replacement of in-line filters is developed and followed as part of a containment zone maintenance plan to verify that filters continue to function as intended and to prevent a breach of containment. This test is intended to verify the performance of filters where present in accordance with requirements 3.5.4, 3.7.8, 3.7.9, and 3.7.16.
5.1.4	Validation of decontamination technologies and processes confirms the proper functioning of the equipment and the effective decontamination of materials prior to their disposal or removal from the containment zone. In cases where biological or chemical indicators are not appropriate (i.e., prions), parametric monitoring devices can be used to accurately monitor the performance of decontamination equipment. Examples include thermocouples and gauges that capture cycle time, temperature, and pressure. A thermocouple is an application-specific parametric device for the validation of heat-based decontamination technologies (e.g., autoclaves) when used for inactivating prions. This test is intended to verify the performance of decontamination technologies in accordance with requirements 3.7.11, 3.7.12, 3.7.13, and 4.8.10.
5.1.5	Testing of Class II BSCs to confirm they operate as intended prevents personnel exposure resulting from a breach of containment. This test is intended to verify the performance of Class II BSCs where present in accordance with requirements 3.7.1, 3.7.2, 3.7.3, and 4.6.15.
5.1.6	Testing of BSCs and custom ventilated enclosures to confirm they operate as intended prevents personnel exposure resulting from a breach of containment. This test is intended to verify the performance of BSCs and custom ventilated enclosures where present in accordance with requirements 3.7.1, 3.7.2, 3.7.3, and 4.6.15.

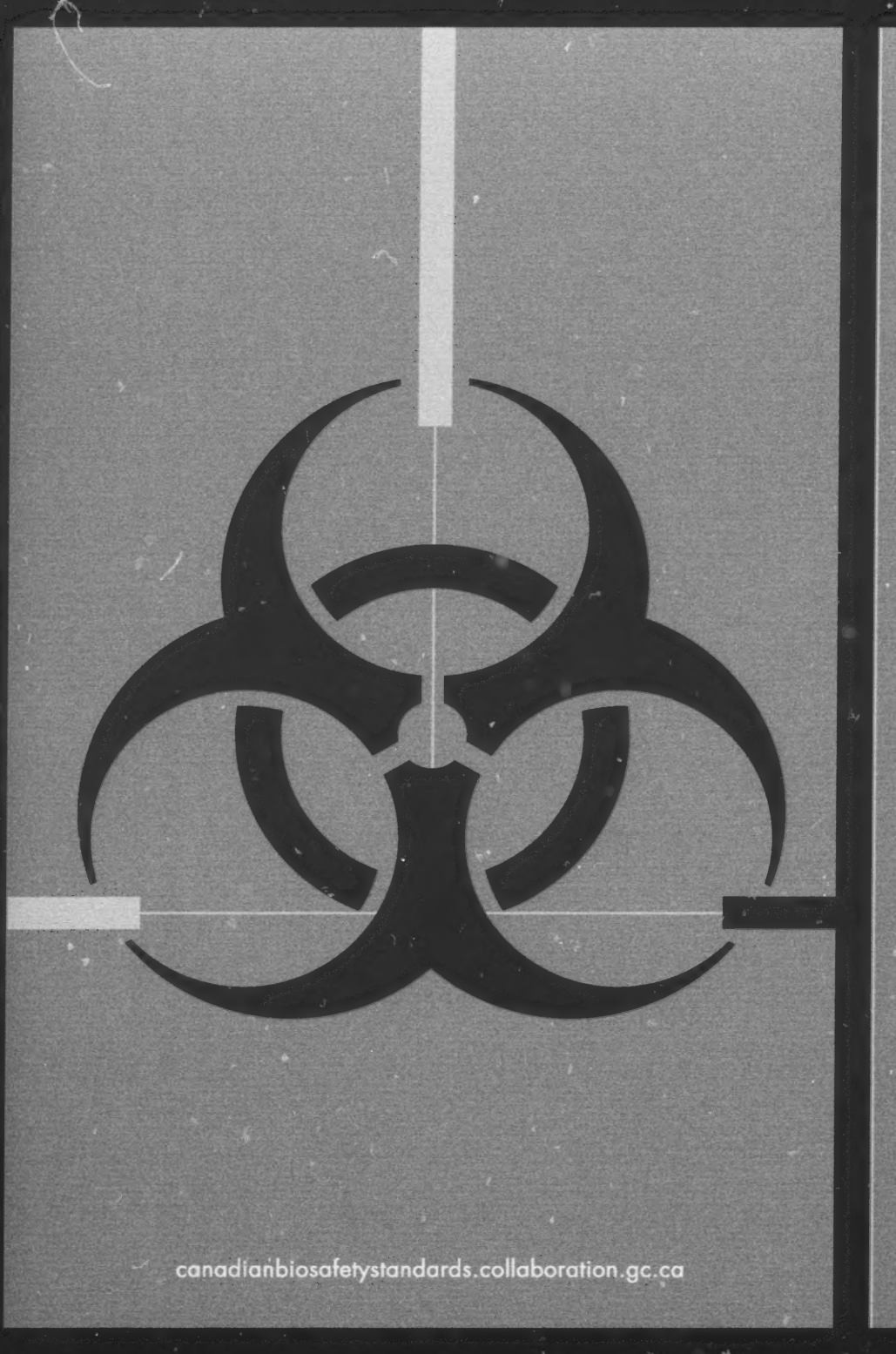
Requirement Number(s)	Explanatory Note
5.1.7	Testing of primary containment devices to confirm they operate as intended prevents personnel exposure resulting from a breach of containment. This test is intended to verify the performance of primary containment devices, other than a BSC, where present in accordance with requirements 3.7.1, 3.7.2, 3.7.4, 3.7.8, and 3.7.9.
5.2.1	Conducting regular performance and verification tests provides proof that the containment systems are functioning as designed and intended and that the minimal acceptable criteria continue to be met. Reports of each test provide a record that demonstrates the appropriate test(s) have been performed. Testing frequency is based on the risks associated with equipment malfunctioning or failing, and is higher for higher containment levels. Tests are performed following any changes, repairs, or modifications to any component that may affect the containment system to confirm it continues to function as intended before operation involving pathogens and toxins resumes.
5.2.2	Conducting regular performance and verification tests provides proof that the containment systems are functioning as designed and intended and that the minimal acceptable criteria continue to be met. Reports of each test provide a record that demonstrates the appropriate test(s) have been performed. Testing frequency is based on the risks associated with equipment malfunctioning or failing, and is higher for higher containment levels. Tests are performed following any changes, repairs, or modifications to any component that may affect the containment system to confirm it continues to function as intended before operation involving pathogens and toxins resumes.
5.2.3	Controlled access and security systems restrict access to the containment zone(s) to authorized personnel only. Verification confirms that the controlled access systems operate as designed, such that a correct code, card, or biometric trait allows access and an incorrect code, card, or biometric trait does not. Verification of other security systems (e.g., closed circuit television) confirms that they operate as specified. If key locks are used, verification can also include verifying that keys are only distributed to authorized personnel and that they are non-reproducible. This test is intended to verify the performance of controlled access and security systems, where installed in accordance with requirements 3.3.4, 3.3.5, 3.3.6, 3.3.7, and 3.3.8.

Requirement Number(s)	Explanatory Note
5.2.4	Containment systems used in high containment zones (including, but not limited to, controls, fans, critical containment devices, communication devices, and effluent decontamination systems) are critical for personnel and environmental safety. Testing of the emergency power and UPS systems under representative electrical load conditions confirms that all critical containment systems will continue to operate during a power outage. If live load testing is not possible, simulated load testing is acceptable. This test is intended to verify the performance of emergency power and UPS systems, where present in accordance with requirements 3.6.18 and 3.6.19.
5.2.5	Communication systems allow the transmission of information in and out of the containment zone, and are especially essential in the event of an emergency. Verification of communication systems confirms that they operate as intended. This test is intended to verify the performance of communication systems installed in accordance with requirement 3.7.18.
5.2.6	Intact seals and surfaces maintain the containment barrier, and allow areas or surfaces to be effectively decontaminated. A visual inspection allows the identification of areas that have lost their integrity and that need repair. A visual inspection includes verifying floors, walls, and ceilings, as well as floor/wall and wall/ceiling joints for cracks, chips, and wear. Identifying surfaces on the containment barrier that have lost their integrity is essential to protect personnel from exposure and to prevent a breach of containment. This test is intended to verify the performance of seals and surfaces in accordance with requirements 3.2.6, 3.2.10, 3.2.11, 3.2.12, 3.4.1, 3.4.2, 3.4.4, 3.4.7, 3.4.8, and 3.4.9 as applicable.
5.2.7	Visually demonstrating IDA at all critical doors on the containment barrier will verify that air flows toward areas of higher containment, according to design, and never the reverse. This test is intended to verify that IDA is provided in accordance with requirements 3.5.1, 3.5.2, and 3.8.6.
5.2.8	Testing of HEPA filters confirms their integrity and prevents a breach of containment and the release of infectious aerosols or aerosolized toxins from the containment zone. This test is intended to verify the performance of HEPA filters installed in accordance with requirements 3.5.6, 3.5.7, 3.5.8, 3.5.10, 3.5.11, 3.5.12, 3.6.12, 3.6.13, 3.6.14, 3.7.9, 3.8.12, and 3.8.13.

Requirement Number(s)	Explanatory Note
5.2.9	Properly functioning door interlocks prevent the simultaneous opening of two doors, which could lead to a breach of containment, while properly functioning emergency overrides are critical in emergency situations. Verification of door interlocks confirms that the interlocks operate as designed, and that associated emergency manual overrides release all interlocks when activated. Door interlocks can be tested by opening the critical door and attempting to simultaneously open the associated interlocked doors. Door interlocks are tested one at a time, in both directions. This test is intended to verify the performance of door interlocks and associated manual overrides installed in accordance with requirements 3.2.7, 3.2.8, 3.2.9, 3.3.17, 3.3.18, and 3.3.19.
5.2.10	Testing of the low level alarm of chemical decontamination technologies confirms that the alarm is triggered when the level of disinfectant drops below the minimum set point. Testing of other alarms in decontamination technologies confirms that they function as designed. This test is intended to verify the performance of alarms on decontamination technologies present in accordance with requirements 3.2.7, 3.2.8, 3.2.9, 3.7.16, and 3.8.8.
5.2.11	Testing of water supply backflow preventers (e.g., reduced pressure backflow preventers) confirms that they are working as intended and protect the main water supply from contamination in the event of a reversal of water from the containment facility. This test is intended to verify the performance of backflow prevention installed in accordance with requirement 3.6.3.
5.2.12	Testing the integrity of seals of containment barrier penetrations, animal cubicle penetrations, and PM room penetrations, including all conduits and wiring, as well as seals around doors, windows, and pass-through technologies including autoclaves and dunk tanks, with a smoke pencil identifies seals that have lost their integrity and that need repair. Identifying surfaces on the containment barrier that have lost their integrity is essential to protect personnel from exposure and to prevent a breach of containment. This test is intended to verify the seals present in accordance with requirements 3.2.6, 3.2.10, 3.2.11, and 3.2.12.

Requirement Number(s)	Explanatory Note
5.2.13	Testing of compressed breathing air and associated systems, including the switchover to backup system and alarm response, confirms that they operate as intended and helps prevent personnel exposure. This test is intended to verify the performance of compressed breathing air and associated systems in accordance with requirements 3.6.15 and 3.6.16.
5.2.14	Testing of positive-pressure suits, including a visual inspection of seams, closures, gaskets, joints and pressure testing by suit inflation, confirms that they operate as intended and helps prevent personnel exposure. This test is intended to verify the integrity of positive-pressure suits worn in the containment zone in accordance with requirement 4.4.8.
5.2.15	Testing of chemical decontamination shower systems in the containment zone, including verification that the appropriate concentration or volume of disinfectant is discharged, chemical level and conductivity meters function as intended, and that the timer (if applicable) reaches the minimum set time, confirms that they operate as designed. Testing of the low level alarm confirms that the alarm is triggered when the level of disinfectant drops below the minimum set point. This test is intended to verify the performance of chemical decontamination shower systems and associated parametric monitoring and recording devices and alarms installed in accordance with requirements 3.3.16, 3.7.14, and 3.7.16.
5.3.1	Drainage piping is tested in accordance with the *National Plumbing Code of Canada* to confirm that the system is working correctly. Testing includes all drains and associated piping, as well as associated vent lines connected to the effluent decontamination system. This test is intended to verify the performance of drain piping installed in accordance with requirement 3.6.10.

Requirement Number(s)	Explanatory Note
5.3.2	Testing of HEPA filter housings confirms their integrity and prevents a breach of containment and the release of infectious aerosols or aerosolized toxins from the containment zone. This test is intended to verify the integrity of HEPA filter housings installed in accordance with requirement 3.5.14.
5.3.3	HVAC and HVAC control systems are critical for environmental safety and personnel safety. Testing the HVAC system and HVAC system components through a variety of failure scenarios demonstrates that these systems can continue to prevent a breach of containment and the release of infectious aerosols or aerosolized toxins from the containment barrier, even in the event that one or more components of the system fails. These tests are intended to verify the performance of the HVAC system and HVAC system components and features in accordance with requirements 3.5.1, 3.5.2, 3.5.3, 3.5.4, 3.5.5, 3.5.9, 3.5.18, and 3.7.3, as applicable.
5.3.4	Testing of containment zone ductwork confirms its integrity and prevents a breach of containment and the release of infectious aerosols or aerosolized toxins from the containment zone. This test is intended to verify the integrity of the supply air and exhaust air ductwork installed in accordance with requirements 3.5.7, 3.5.8, 3.5.16, and 3.5.17.
5.3.5	Integrity of the containment barrier in containment zones where doors can be sealed (CL3-Ag and CL4) is verified by pressure decay testing. Identifying surfaces on the containment barrier that have lost their integrity is essential to protect personnel from exposure and to prevent a breach of containment. This test is intended to verify the integrity of the containment zone designed in accordance with requirements 3.2.6, 3.2.11, 3.2.12, 3.3.20, and 3.3.21.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